

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re MEDTRONIC, INC. SECURITIES LITIGATION) Master File No. 0:13-cv-01686-JRT-FLN
)
) CLASS ACTION
)
This Document Relates To:) CONSOLIDATED CLASS ACTION
) COMPLAINT FOR VIOLATION OF
) THE FEDERAL SECURITIES LAWS
)
) ALL ACTIONS.)
)
) DEMAND FOR JURY TRIAL

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SUMMARY OF THE ACTION

1. This is a securities class action brought on behalf of all persons who purchased or otherwise acquired Medtronic, Inc. (“Medtronic” or the “Company”) common stock between September 28, 2010, and August 3, 2011, inclusive (the “Class Period”). The claims asserted herein are brought against Medtronic and certain of its current and/or former officers and executives, and certain of its paid consultants, for violations of the Securities Exchange Act of 1934 (“1934 Act”), including William A. Hawkins (“Hawkins”), former Chairman of the Board of Directors (“Board”) and Chief Executive Officer (“CEO”); Gary L. Ellis (“Ellis”), Chief Financial Officer (“CFO”); and Richard E. Kuntz (“Kuntz”), Chief Scientific, Clinical and Regulatory Officer.

2. Medtronic, headquartered in Minneapolis, Minnesota, is engaged in medical technology. The Company’s stock trades on the New York Stock Exchange (“NYSE”) under the ticker symbol MDT. According to the Company’s filings with the U.S. Securities and Exchange Commission (“SEC”), Medtronic develops, manufactures, and markets medical devices worldwide.

3. Prior to and during the Class Period, defendants engaged in a scheme to defraud and issued false and misleading statements regarding the Company’s true financial condition. Specifically, the Company misrepresented and or concealed material facts in connection with the safety and efficacy of INFUSE, a product containing recombinant human bone morphogenetic protein (“rhBMP-2”) used for spinal surgeries. As a result of defendants’ conduct alleged herein, Medtronic’s stock traded at artificially inflated prices during the Class Period, reaching a high of \$43.20 per share on May 18, 2011. In truth,

defendants knew but concealed from the investing public that the Company was engaged in a longstanding scheme to downplay or conceal altogether the known risks and adverse side effects associated with INFUSE and INFUSE-related products, including its possible link to cancer.

4. On May 25, 2011, *The Spine Journal*, the official journal of the North American Spine Society, began publishing a series of new studies which revealed true facts concerning the health and safety risks of INFUSE. On June 28, 2011, *The Spine Journal* dedicated an entire issue to new critical studies of INFUSE, including disclosure of massive financial conflicts of interest by researchers who had published initial studies finding that the product was safe. Moreover, *The Spine Journal* identified that the incidence of adverse events experienced in connection with INFUSE's use (events which were previously undisclosed) was between **10 and 50 times** the rates published in industry-supported studies, and included male sterility, infection, bone loss and unwanted bone growth. These disclosures caused the artificial inflation in Medtronic's stock price to begin to dissipate, sending the stock price down almost 25% from its Class-Period high.

5. Later, in October 2012, an investigation by the United States Senate Finance Committee uncovered evidence revealing that Medtronic had in fact heavily edited the content of journal articles which were purportedly authored by physician consultants and had not disclosed adverse events associated with INFUSE. Further, the Senate investigation disclosed that Medtronic had paid approximately **\$210 million** to physician authors of Medtronic-sponsored studies and such payments had not been fully disclosed by Medtronic.

6. The unlawful conduct and misrepresentations alleged herein caused hundreds of millions of dollars in economic damages to investors in the Company's publicly-traded common stock.

BACKGROUND AND OVERVIEW

7. Well before the Class Period, the Company developed a new product, the INFUSE bone graft, an addition to its spinal unit products and therapies. INFUSE is the trade name of rhBMP-2, a bone morphogenetic protein ("BMP") that induces the body to form bone tissue. INFUSE was positioned by Medtronic as an alternative to harvesting bone from the patient's own body (autograft), or using donated bone tissue (allograft), or other synthetic bone substitutes. Medtronic's INFUSE was a first-to-market BMP that was sold as part of a kit called the INFUSE Bone Graft/LT-Cage. INFUSE Bone Graft/LT-Cage is a component system that consists of a hollow titanium cylinder (the LT-Cage) and rhBMP-2 (INFUSE), which is placed on an absorbable collagen sponge and inserted into the LT-Cage and then placed in the patient's spine.

8. In July 2002, the U.S. Food and Drug Administration ("FDA") approved the use of INFUSE Bone Graft/LT-Cage for the treatment of degenerative disc disease. INFUSE's approval indication was narrow: it was to be used ***only*** in single-level fusions, ***only*** between L4 and S1 (the lumbar spine, *i.e.*, the lower back), and ***only*** via an anterior approach. This procedure is known as anterior lumbar interbody fusion ("ALIF"). Although INFUSE was later approved for use in dental surgery and for the repair of certain tibial (shin) fractures, INFUSE has never been approved for any spinal fusion indication other than ALIF surgeries.

9. Prior to FDA approval in 2002, Medtronic had set a corporate goal to have INFUSE replace iliac crest bone graft (“ICBG”) as the standard of care in spinal fusion. For INFUSE to become the standard of care and drive sales, its safety and efficacy needed to be supported by clinical evidence. That is, Medtronic needed clinical studies that showed that patients who used INFUSE had better results and less adverse side effects compared to patients undergoing more traditional bone graft procedures.

10. Between approximately 2005 and 2010, Medtronic vastly expanded the proportion of its research and development budget which was spent on “clinical studies, on evidence-based medicine,” and defendants knew that clinical studies which purported to demonstrate the efficacy of Medtronic products were critical to the Company’s success.

11. In a November 23, 2010 conference call announcing Medtronic’s 2Q11 financial results, Hawkins claimed that Medtronic was “extending our leadership in the area of generating meaningful clinical evidence, which is ***critical*** to expanding our markets, accelerating adoption to our therapies, differentiating our competitive position, and creating new markets.”

12. On a January 6, 2011 Goldman Sachs healthcare conference call, Hawkins elaborated further, stating that:

So when you get evidence and if you have technology that you can demonstrate that clinically makes a difference and does reduce hospitalizations and keeps – and works, I mean ***the market will pay for that***. And ***that is how we have gotten to where we are and that is how I believe we are going to get to where we are going to try to go to***. And so we just have got to be much more smart about choosing the right products and making sure that we have the evidence underpinning them as we launch them into the marketplace. And then ***price becomes less of a discussion***.

13. Hawkins also specifically attributed Medtronic's ability to charge higher prices to being able to "***demonstrate value through evidence and through clinical studies.***"

14. Days later, Hawkins attributed Medtronic's "competitive advantage" to the Company having "[a]rguably . . . one of the strongest clinical enterprises which, as we all know in this environment, evidence-based management or medicine is going to be a ***key basis of competition and of sustainability.***" Hawkins further stated that "differentiated technology" supported by "[s]uperior evidence" was key to the Company's ability to "win in our existing markets."

15. However, early INFUSE clinical studies designed and sponsored by Medtronic revealed significant safety risks that would threaten Medtronic's corporate goal of replacing ICBG as the standard of care. Knowing these facts, the Company embarked on a scheme with physician investigators and authors to conceal the significant safety risks from the public and physician community.

16. As alleged herein, in order to induce physician acceptance and generate consistent sales growth of INFUSE, the Company forged relationships, including financial relationships, with physician authors who published research articles in respected medical journals and knowingly concealed in those original articles, or omitted altogether, known facts regarding INFUSE's adverse side effects observed in clinical trials. The same research articles overstated apparent disadvantages of alternative bone graft procedures (for example, pain associated with traditional bone graft harvesting), as opposed to treatment with INFUSE. The articles thereby advanced the false notion that INFUSE was superior to those procedures.

17. In addition to failing to disclose known, serious adverse events and side effects of INFUSE, Medtronic and the Consultant Defendants (defined below) knew but failed to disclose that Medtronic had paid millions of dollars to the same physician authors and that during the drafting process, Medtronic employees heavily edited the articles and specifically excised true facts learned during clinical trials about the efficacy and side effects of INFUSE, which would have alerted the public and physicians using INFUSE about its harmful side effects and lack of clinical benefit.

18. As a result of the above-described scheme and course of conduct, defendants caused the publication of the original industry-sponsored clinical research studies to report almost zero adverse events or side effects connected with INFUSE. As reported in the June 28, 2011 issue of *The Spine Journal* and excerpted below, each of the thirteen early industry-sponsored rhBMP-2 clinical studies failed to report adverse events related to INFUSE:

Table 1

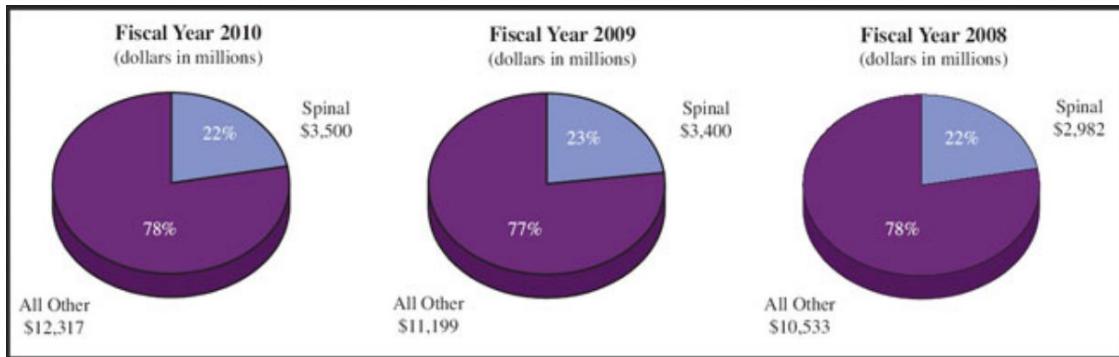
Original industry-sponsored rhBMP-2 clinical studies and reported adverse event rates because of rhBMP-2

Authors	rhBMP-2 Placement	rhBMP-2, n	rhBMP-2 Adverse events (%)	Authors comments regarding rhBMP-2– related observed adverse events in study patients
Boden et al. [2]	Anterior interbody (LT-cage, lumbar, rhBMP-2)	11	0	<i>“There were no adverse events related to the rhBMP-2 treatment”</i>
Boden et al. [3]	Posterolateral (lumbar, ± instrumentation)	20	0	<i>“There were no adverse effects directly related to the rhBMP-2...”</i>
Burkus et al. [5]	Anterior interbody (LT-cage, lumbar, INFUSE)	143*	0	<i>“There were no unanticipated device-related adverse events...”</i>
Burkus et al. [6]	Anterior interbody (bone dowel, lumbar, INFUSE)	[24] [±]	0	<i>“There were no unanticipated adverse events related to the use of INFUSE Bone Graft.”</i> (2002)
Burkus et al. [39]		79	0	<i>None reported</i> (2005)

19. Due to industry-sponsored literature that reported ***no adverse events*** attributed to INFUSE, spine surgeons began using INFUSE for an array of procedures including in the cervical spine (*i.e.*, the neck), multi-level fusions, in higher-than-approved dosages, and with a posterior or cross-body approach. Sales and revenue growth was explosive. According to

the June 28, 2011 *The Spine Journal* article titled “A Critical Review of Recombinant Human Bone Morphogenetic Protein-2 Trials in Spinal Surgery: Emerging Safety Concerns and Lessons Learned” (“Critical Review”), the number of spine fusions augmented by rhBMP-2 soared from 0.7% in 2002 to 25% in 2006. Ex. A.

20. For fiscal year 2010 (“FY10”), ending April 30, 2010, the Company reported that its spinal segment, which included biologics such as bone growth substances, including INFUSE, generated more than \$3.5 billion in revenues and that in 2008, 2009 and 2010, the Company’s Spinal Division delivered 22%, 23% and 22% in each year, respectively.



21. Notwithstanding that early medical literature failed to disclose known serious side effects associated with INFUSE, over the years following its approval, observational studies reported serious adverse effects which appeared to be related INFUSE. For example, in 2008, the FDA issued a warning letter regarding off-label use of INFUSE, specifically warning that the use of INFUSE in the cervical spine had been linked to severe and

potentially life-threatening complications, including swelling of the neck and throat tissue, and reports of difficulty swallowing, breathing or speaking.¹

22. The Company also concealed known risks associated with its second-generation BMP, called AMPLIFY, knowing that disclosure of such risks would affect not only AMPLIFY's pending application for market approval, but INFUSE sales as well. AMPLIFY and INFUSE were composed of the identical bone-growth inducing protein; however, AMPLIFY would be available in a 40-mg dose, whereas INFUSE's maximum dose was 12 mg. In July 2010, questions concerning the possible cancer risks of AMPLIFY were raised by government reviewers who cited a study indicating that patients treated with AMPLIFY had a higher rate of developing cancer than those who were not treated with AMPLIFY. As reported by the *Minnesota Star Tribune* on July 23, 2010, Medtronic responded to the report by stating that cancer risks were not statistically different between the group that was treated with AMPLIFY and the group that was not.

23. Lawsuits and investigations mounted in connection with usage of INFUSE, including off-label promotion of INFUSE and potential cancer risks associated with the product. Medtronic settled these claims (some brought by Medtronic employees), all the while continuing to deny wrongdoing and concealing the true facts, particularly that the medical community and public's reliance on the literature published in medical journals concerning INFUSE was wholly unwarranted because Medtronic improperly influenced

¹ In November 2008, the U.S. Department of Justice ("DOJ") opened an investigation into Medtronic's possible participation in marketing INFUSE for off-label uses. In May 2012, the DOJ closed the investigation without charges and without a settlement.

physician authors to suppress known risks related to INFUSE in those purportedly peer-reviewed research articles and that Medtronic itself edited those articles to remove reference to those risks.

24. In addition, in furtherance of the scheme to advance FDA approval of INFUSE-related products like AMPLIFY, and to continue the concealment of the true adverse effects associated with it, Medtronic made independent, knowingly materially-false statements prior to and during the Class Period. These misrepresentations included, among other things, claims that the Company's overall clinical studies "show the safety, efficacy, and cost effectiveness of [Medtronic's] therapies," that Medtronic sets "the standard for quality in the industry," and that Medtronic's internal controls were effective to reveal fraud. Defendants also concealed the fact that the FDA rejected AMPLIFY and made false denials concerning what Medtronic and Zdeblick knew about side effects caused by INFUSE.

25. As a result of defendants' scheme and independent false and misleading statements during the Class Period, Medtronic's stock traded at artificially inflated prices during the Class Period, reaching a high of \$43.20 per share on May 18, 2011.

26. The full scope of defendants' scheme and misrepresentations began to be fully revealed through several partial disclosures between May 2011 and August 2011. For example, on May 25, 2011, shortly after midnight, *The Spine Journal* published a study highlighting the risk of male infertility in connection with the use of INFUSE and questioning industry-sponsored publications that failed to report such risks. The new study found a high, statistically-important incidence of retrograde ejaculation (a condition that causes sterility) in male patients treated with INFUSE. The researchers *found and reported*

that 7.2% of patients who had been treated with INFUSE developed retrograde ejaculation as opposed to 0.6% who did not receive INFUSE – a twelve-fold difference. Ex. B at 2.

27. The May 25, 2011 *The Spine Journal* articles were immediately published in the traditional news media, including *Bloomberg* and *The New York Times*, as well as reported by securities analysts. Each specifically noted that *none of the Medtronic-funded studies even mentioned the risk of retrograde ejaculation*:

- May 25 (*Bloomberg*) – Medtronic Inc.’s INFUSE, a genetically engineered protein used to spur the growth of new bone after spinal surgery, *increases the risk of infertility in men following some operations, researchers said*.
- May 25 (*The New York Times*) – Among the 69 patients treated by Dr. Eugene Carragee (“Carragee”) who received INFUSE, five men developed the complication related to sterility, *in contrast to one patient among the 174 men who received a bone graft. That finding is in stark contrast to earlier research by doctors paid by Medtronic, who found no connection between the product, INFUSE, and a condition that causes sterility.*²

28. Even in the face of the May 25, 2011, *The Spine Journal* publication of the results of these new independent studies, the Company and Dr. Thomas A. Zdeblick (“Zdeblick”), who was responsible for publishing certain initial research articles, made knowingly false statements regarding the reason why the incidence of retrograde ejaculation observed in the early clinical trials were not reported in those initial articles, and suggested that the May 25 *The Spine Journal* study was misleading:

- Medtronic: “[I]n the original study that supported FDA approval of INFUSE, infertility problems *were not common enough to be statistically linked to the product.*”

² Here, as elsewhere, emphasis has been added, unless otherwise noted.

- Zdeblick: *The Spine Journal* study was interesting but does not constitute truth. ***Retrospective trials are notorious for being misleading.*** “Carragee’s Study has ‘numerous flaws.’”

29. Following the disclosure of the May 25, 2011 *The Spine Journal, Bloomberg* and *The New York Times* articles, reporting on the previously under-reported and not widely-known fact that INFUSE could cause retrograde ejaculation, the Company’s stock price declined from a close of \$40.88 on May 24, 2011, to a close of \$40.23 on May 25, 2011, but remained artificially inflated due to continued misrepresentations and concealment of the true facts.

30. One month later, on June 28, 2011, an entire issue of *The Spine Journal* was devoted to INFUSE, including the conflicts of interest by researchers who had performed studies on INFUSE and the risks and side effects associated with INFUSE. *The Spine Journal* authors noted that in contrast to the industry-sponsored studies, the incidence of adverse events experienced in connection with INFUSE’s use ***was 10 to 50 times what had been reported by industry-funded sources and included male sterility, infection, bone loss, and unwanted bone growth:***

As of March 2011, of the 13 original studies, there was one study with no information available regarding the authors financial relationship with the rhBMP-2 manufacturer. ***Of the remaining 12 studies, the median-known financial association between the authors and Medtronic Inc. was found to be approximately \$12,000,000–\$16,000,000 per study (range, \$560,000–\$23,500,000).***

31. Another article published in the June 28, 2011 *The Spine Journal* titled “Resetting Standards for Sponsored Research: Do Conflicts Influence Results?” noted that information reported in medical journals following INFUSE’s approval by the FDA played

down the product's risks and slanted the articles in favor of the use of INFUSE over bone grafts.

32. On June 29, 2011, J.P. Morgan issued a report titled "Infuse in the Crosshairs; Lowering Estimates" discussing the shocking information published in the June 28, 2011 issue of *The Spine Journal*. The J.P. Morgan report focused on the new disclosures, specifically adverse side effects (likely caused by INFUSE) and conflicts of interest with physician authors who wrote initial journal articles:

- ***"systematic underreporting of adverse events in the clinical studies supporting Infuse's US approval";***
- ***"faulty trials designs"; and***
- ***"widespread [undisclosed] financial conflicts of interest among the surgeons who participated in the studies and reported the results."***

33. Following the disclosures in the June 28, 2011, *The Spine Journal* issue, Medtronic's stock declined \$0.92 per share to close at \$38.09 per share on June 29, 2011, a one-day decline of nearly 3% on volume of 10 million shares.

34. Securities analysts continued to study the disclosures of June 28, 2011, and surveyed doctors and their likelihood to use INFUSE. On July 5, 2011, Wells Fargo Securities, LLC ("Wells Fargo") published a report stating: ***"[W]e think spine surgeons will use other bone growth products in their fusion procedures We See About A 25% Chance InFuse Is Pulled From The Market."*** That day, Medtronic's stock price fell to below \$38 per share.

35. The June 28, 2011 disclosures in *The Spine Journal* also triggered additional investigations by the U.S. Senate Finance Committee into the Company's financial

relationships with physician authors who published the initial medical research. In October 2012, the U.S. Senate Committee on Finance issued a Staff Report on Medtronic's Influence on INFUSE Clinical Studies ("Senate Report") that confirmed facts in connection with the alleged scheme and specifically Medtronic's undisclosed influence on INFUSE medical journal articles which purported to report on INFUSE clinical studies. Ex. C. The Senate Report, drafted after the Committee reviewed internal documents and e-mails produced by Medtronic, included the following findings, among others, demonstrating the Company's knowing misconduct:

- *Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic.*
- *Medtronic officials inserted language into studies that promoted InFuse as a better technique than taking a bone graft from the pelvic bone* (autograft technique) by emphasizing the pain of the autograft technique.
- Medtronic employee recommended against publishing a complete list of adverse events possibly associated with INFUSE in a 2005 *Journal of Bone & Joint Surgery* article.
- Medtronic prepared Dr. Hal Mathew's remarks to the FDA advisory panel meeting prior to INFUSE being approved. At the time, Dr. Mathews was a private physician.

Id. at 2.

36. In addition, as part of the materials produced to the Senate Finance Committee, Medtronic produced a 2001 PowerPoint presentation by Zdeblick that, in fact, reported a 10.3% rate of retrograde ejaculation for those treated with INFUSE that was "*statistically different from the control group.*"

**InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered
Fusion Device
IDE G960065 – Pivotal Trial Results**

Adverse Events (%)

Anatomical/Technical Difficulties	Investigational		Control 1.5
	Open 0.0	Laparoscopic 7.4*	
Back/Leg Pain	16.6	15.4	12.5
Gastrointestinal	17.9	9.6	11.8
Infection	7.6	10.3	6.6
Neurological	7.6	8.8	10.3
Retrograde Ejaculation	6.3	10.3*	1.5
Spinal Event	8.3	2.9	8.1
Subsidence	2.8	0.7	0.0
Trauma	13.1	14.0	16.9

*Statistically different from control

37. The 2001 PowerPoint slide confirms defendants' actual knowledge of false denials made by the Company and Zdeblick on May 25, 2011, that the incidence of retrograde ejaculation was not statistically different from the control group.

38. As discussed herein, defendants' scheme and independent misrepresentations during the Class Period, which served to further advance the scheme, caused hundreds of millions of dollars in losses to investors as the truth began to be more fully revealed.

JURISDICTION AND VENUE

39. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 (17 C.F.R. §240.10b-5) promulgated thereunder by the SEC.

40. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act (15 U.S.C. §78aa).

41. Venue is proper in this District pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b), as many of the acts and practices complained of herein occurred in substantial part

in this District. Medtronic maintains its principal place of business in this District, and certain of the acts and conduct complained of herein, including dissemination of materially false and misleading information to the investing public, occurred in this District.

42. In connection with the acts alleged herein, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

43. Lead Plaintiff Employees' Retirement System of the State of Hawaii ("Hawaii ERS") purchased Medtronic common stock during the Class Period and was damaged by the conduct alleged herein.

44. Lead Plaintiff Union Asset Management Holding AG ("Union Asset") purchased Medtronic common stock during the Class Period and was damaged by the conduct alleged herein.

45. Plaintiff West Virginia Pipe Trades Health & Welfare Fund purchased the common stock of Medtronic during the Class Period and was damaged by the conduct alleged herein.

46. Defendant Medtronic develops, manufactures, and markets medical devices worldwide. Medtronic maintains its headquarters at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. The Company's stock trades on the New York Stock Exchange ("NYSE") under the ticker MDT.

47. Defendant William A. Hawkins was, at all relevant times alleged herein, the Company's CEO and Chairman of the Board until he retired from the Company in June 2011. Hawkins was a Director of Medtronic since March 2007 and Chairman and CEO since August 2008. He served as President and CEO of Medtronic from August 2007 to August 2008 and as President and Chief Operating Officer from May 2004 to August 2007. Hawkins served as Senior Vice President and President of Medtronic Vascular from January 2002 to May 2004. Defendant Hawkins was compensated more than \$9 million per year for fiscal 2010 and fiscal 2011.³

48. Defendant Gary L. Ellis was, at all relevant times alleged herein, the Company's CFO and Senior Vice President. Ellis has been Senior Vice President and CFO since May 2005. Prior to that, he had been Vice President, Corporate Controller and Treasurer since October 1999, and Vice President Corporate Controller from August 1994 to October 1999. Mr. Ellis joined Medtronic in 1989 as Assistant Corporate Controller and was promoted to Vice President of Finance for Medtronic Europe in 1992 until being named as Corporate Controller in 1994. Defendant Ellis was compensated more than \$3 million in each of fiscal 2010 and 2011.

49. Defendant Richard E. Kuntz was, at all relevant times alleged herein, the Company's Senior Vice President and Chief Scientific Clinical and Regulatory Officer, a position he has held since August 2009. Prior to that, he was Senior Vice President and President of Neuromodulation from October 2005 to August 2009, and prior to that was an

³ Medtronic's fiscal year ends the last Friday in April.

interventional cardiologist and Chief of the Division of Clinical Biometrics at Brigham and Women's Hospital, Associate Professor of Medicine and Chief Scientific Officer of the Harvard Clinical Research Institute.

50. Defendant Julie Bearcroft, Ph.D. ("Bearcroft") was, at relevant times alleged herein, Director of Technology Management in Medtronic's Biologics Marketing Department and participated in the alleged scheme to conceal the true facts concerning the adverse side effects of INFUSE.

51. Defendant Richard W. Treharne, Ph.D. ("Treharne") was, at relevant times alleged herein, Senior Vice President of Clinical and Regulatory Affairs at Medtronic and participated in the alleged scheme to conceal the true facts concerning the adverse side effects of INFUSE.

52. Defendant Martin Yahiro, M.D. ("Yahiro") was, at relevant times alleged herein, a Medtronic Senior Director of Regulatory Affairs and participated in the alleged scheme to conceal the true facts concerning the adverse side effects of INFUSE and INFUSE-related products including AMPLIFY.

53. Defendant Dr. Thomas A. Zdeblick was, at relevant times alleged herein, a physician consultant for Medtronic, authored certain of the medical journal articles alleged herein and issued materially false and misleading statements during the Class Period in connection with Medtronic-sponsored clinical trials concerning INFUSE. At relevant times Zdeblick served as Editor-in-Chief of the *Journal of Spine Disorders* and, as alleged herein, participated in the scheme to conceal the true facts concerning adverse side effects of INFUSE and INFUSE-related products. The Senate Report reflects that Medtronic paid

Zdeblick over \$34 million through 2010, and it is alleged he continued to receive millions during the Class Period.

54. Defendant Dr. J. Kenneth Burkus (“Burkus”) was, at relevant times alleged herein, a physician consultant for Medtronic and authored certain of the relevant medical journal articles alleged herein. As alleged herein, Burkus participated in the scheme to conceal the true facts concerning adverse side effects of INFUSE and INFUSE-related products. The Senate Report reflects that Burkus received over \$6 million from Medtronic through 2010, and he is alleged to have continued to receive payments during the Class Period.

55. Defendant Dr. Scott D. Boden (“Boden”) was, at relevant times alleged herein, a physician consultant for Medtronic and authored certain of the relevant medical journal articles alleged herein. As alleged herein, Boden participated in the scheme to conceal the true facts concerning adverse side effects of INFUSE and INFUSE-related products. Boden received over \$28 million from Medtronic through 2010.

56. The defendants named above in ¶¶47-52 are referred to herein as the “Individual Defendants.”

57. The defendants named above in ¶¶53-55 are referred to herein as the “Consultant Defendants.”

CONTROL PERSONS

58. As officers and controlling persons of a publicly-held company whose common stock was and is traded on the NYSE and is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate

accurate and truthful information regarding the Company's financial condition, performance, growth, operations, financial statements, business, markets, management, earnings, present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue so that the market price of the Company's common stock would be based upon truthful and accurate information. The Individual Defendants' material misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

59. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of their Board membership and/or executive and managerial positions with Medtronic, each of the Individual Defendants had access to the adverse undisclosed information about Medtronic's financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Medtronic and its business (or adopted by the Company) materially false and misleading.

60. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the

documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected.

61. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein.

UNRELATED INFUSE CONTROVERSIES

62. Leading up to the Class Period, INFUSE (and Medtronic and its paid consultants) were at the center of a number of seemingly unrelated controversies. While the Company was party to a number of lawsuits and paid tens of millions of dollars and entered into agreements requiring the Company to change its corporate practices, the Company denied any wrongdoing and maintained that it conducted itself in accordance with the law, ethics and regulations governing its business.

63. These controversies, while unrelated to the fraud alleged herein, nevertheless, alerted defendants that the undisclosed scheme and continued concealment of the true facts regarding INFUSE created a risk of misleading the investing public.

Kickbacks to Physicians

64. In July 2006, the Company paid \$40 million to resolve a *qui tam* suit alleging that it had paid illegal kickbacks to physicians who used and promoted INFUSE. That *qui tam* complaint alleged, among other things, that the Company's entry into royalty and consulting agreements was largely a cover to provide illegal kickbacks to doctors who promoted sales of Medtronic products:

Royalty/Product Development Agreements: These are agreements whereby MSD [Medtronic Sofamor Danek] agreed to pay physicians a

percentage of sales of an MSD product . . . were a means of funneling money to physicians to induce them to use MSD products.

* * *

Consulting Agreements: These are allegedly agreements between surgeons and MSD for the surgeons to provide consulting services about MSD products In reality, consulting agreements are nothing more than a vehicle to pay the surgeons

* * *

Research Agreements: MSD entered into agreements to pay doctors that use MSD products for research.

65. As part of that settlement, Medtronic was required to enter into a five-year Corporate Integrity Agreement (“CIA”) with the Health and Human Services’ Office of the Inspector General, which required Medtronic to appoint a Compliance Officer, who would report directly to the CEO, and to implement written policies and procedures addressing the Anti-Kickback Statute and business or financial arrangements that might violate the statute.

66. In July 2008, Medtronic paid \$75 million to resolve another false-claims suit involving its Kyphon product. That settlement also required the Company to enter into another CIA, requiring Anti-Kickback training and policies to be implemented.

Off-label Use

67. On May 13, 2009, *The New York Times* reported that the Army had discovered that Dr. Timothy Kuklo, a former surgeon at Walter Reed Army Medical Center and a paid Medtronic consultant, had falsified data and overstated the benefits of INFUSE in a

published article. On May 21, 2009, the Company announced the suspension of its consulting agreement with Dr. Kuklo.⁴

68. On April 29, 2010, Senator Grassley requested information from Medtronic about financial ties to 32 specific physicians (including Burkus, Zdeblick and others). That request for information encompassed ***2007 to present***, and by its terms, did not contemplate information concerning the influence that the Company had on the earlier literature published by the physician authors concerning INFUSE.

DEFENDANTS' FRAUDULENT SCHEME AND FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

69. Defendants' fraudulent scheme and false and misleading statements operated as a fraud or deceit on purchasers of Medtronic common stock, as they: (i) deceived the investing public regarding Medtronic's products, prospects and business; (ii) artificially inflated the price of Medtronic common stock; and (iii) caused plaintiffs and other members of the Class to purchase Medtronic common stock at artificially inflated prices.

70. On September 28, 2010, the Company filed its Form 10-Q with the SEC for the period ended July 30, 2010. The Form 10-Q was signed by Hawkins and Ellis and stated that the Company designed well-planned clinical studies and that the studies showed the safety and efficacy of the products and therapies:

We work to improve patient access through well-planned studies which show the safety, efficacy, and cost-effectiveness of our therapies, and our alliances with patients, clinicians, regulators, and reimbursement agencies.

⁴ The Senate Finance Committee asked Medtronic why the Company had not disclosed its financial relationship with Dr. Kuklo in response to the earlier request for information. In December 2010, Senator Grassley raised concerns over off-label uses of INFUSE in procedures that were the subject of Dr. Kuklo's articles.

* * *

Expected future growth in our Biologics business, driven by new products such as AMPLIFY, which has been submitted for FDA approval . . .

71. On December 8, 2010, Medtronic filed its Form 10-Q with the SEC for the period ended October 29, 2010. The Form 10-Q was signed by Hawkins and Ellis. The Form 10-Q contained Medtronic's financial results for the second quarter 2011 ("2Q11"), which had been previously reported in a November 23, 2010 press release. With respect to the Company's core device and therapy development, the Company falsely stated that its clinical studies were well-planned and designed to show both the efficacy and safety of its therapies:

We work to improve patient access through ***well-planned studies which show the safety, efficacy, and cost effectiveness of our therapies***, and our alliances with patients, clinicians, regulators, and reimbursement agencies.

* * *

Spinal net sales for the three and six months ended October 29, 2010 were \$850 million and \$1.680 billion, a decrease of 1 percent and 5 percent, respectively, over the same periods in the prior fiscal year.

72. The September 28, 2010 and December 8, 2010 Forms 10-Q included substantially identical false Sarbanes Oxley certifications of both defendants Hawkins and Ellis, pursuant to Sarbanes-Oxley §302 and §906, which stated the following:

1. I have reviewed this Quarterly Report on Form 10-Q of Medtronic, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact ***or omit to state a material fact necessary to make the statements made . . . not misleading*** with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, ***fairly present in all material respects the financial condition . . .;***
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. ***Designed such disclosure controls and procedures . . . to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us . . .;***

* * *

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting . . .; and
 - b. ***Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.***

73. On February 22, 2011, Medtronic issued a press release announcing the Company's third quarter 2011 ("3Q11") financial results. The Company reported earnings of \$922 million, or \$0.86 diluted earnings per share ("EPS"), and revenue of \$3.961 billion for 3Q11. Later that same day, the Company hosted a conference call for analysts and investors during which Hawkins was asked about the Company's new INFUSE-based product, AMPLIFY, whether the FDA might delay its approval, and whether, in the event of

such a delay, INFUSE sales might be negatively impacted. In response, Hawkins falsely suggested that approvability had not yet been determined and, moreover, that even if there were a delay, it would not impact the Company's current business:

[HAWKINS:] [W]e are continuing to work with the FDA to figure out kind of where they are on this. . . . So as we learn more, we will let you know. . . . [If] there was a reason for the FDA to delay this anymore, it is not going to have a significant impact. It won't have any really impact on our current business. It is really all upside for us.

[ANALYST:] [J]ust to clarify that, Bill. You don't feel that not having – like posterior lumbar fusion is probably the biggest off-label to use of INFUSE. And you don't think not getting AMPLIFY approved could result in a retrenchment.

[HAWKINS:] No. . . . I don't see anything that would change as the result of AMPLIFY not getting approved.

74. This statement was knowingly materially false and misleading because, as detailed below in ¶79, the Company had received a letter from the FDA before January 28, 2011, stating that AMPLIFY would not be approved.

75. Later that same day, February 22, 2011, Wells Fargo issued a report regarding the Company's 3Q11 financial results titled "MDT: Lackluster Q3 – Headwinds in ICD's and Spine Remain." The report also discussed the risks associated with the potential for delay in the approval for AMPLIFY and the ongoing DOJ investigation:

In addition to the market challenges, we see risk to MDT's InFuse business given the delay in the approval of Amplify and the potential resolution of the DOJ investigation into off-label promotion.

76. On February 25, 2011, Wells Fargo issued another report titled "InFuse Risks Remain," noting that 70%-80% of INFUSE usage was off-label and also discussing the downside risk to INFUSE sales in connection with the potential DOJ settlement and negative

outlook associated with AMPLIFY. The February 25, 2011 report further indicated that investors had already priced in the likelihood that AMPLIFY would not be approved and a continuing decline in physician usage of INFUSE for off-label uses, *i.e.*, posterior lumbar fusion:

- “Summary. We think there is downside risk to InFuse sales over the next 6-12 months due to”;
- “a likely settlement with the DOJ on the off-label promotion of InFuse”;
- “***the increasingly lower likelihood of Amplify being approved in the US***”; and
- “We think a negative FDA outcome on Amplify and a DOJ settlement on off-label promotion would hurt InFuse sales ***We estimate that 70-80% of InFuse usage is off-label.***”

77. Notwithstanding the February 22, 2011 financial results, Medtronic’s stock price continued to trade at artificially inflated prices above \$40.00 per share on February 23, 2011, and closed at \$39.30 per share.

Defendants Disclose that the FDA Rejected AMPLIFY in the Third Quarter Before the February 22, 2011 Conference Call – Stock Price Declines

78. On March 9, 2011, after the market closed, Medtronic filed its 3Q11 Form 10-Q with the SEC. The Form 10-Q was signed by Hawkins and Ellis and included the same financial results previously reported in its February 22, 2011 press release and again falsely stated that the Company’s “well-planned studies” showed the safety and efficacy of its products and therapies:

We work to improve patient access through ***well-planned studies which show the safety, efficacy, and cost-effectiveness of our therapies, and our alliances with patients, clinicians, regulators, and reimbursement agencies.***⁵

79. In addition, the Company disclosed for the first time that in the “third quarter,” it had received a non-approval letter from the FDA concerning AMPLIFY:

In the third quarter of fiscal year 2011, the FDA sent Medtronic a letter advising that they were ***not able to approve AMPLIFY*** at that time without additional information from Medtronic.

80. Later that same day, March 9, 2011, Wells Fargo issued a report titled “MDT: Amplify Non-Approvable Letter Puts InFuse Sales at Risk.” The March 9, 2011 report noted that the Company had received a non-approvable letter from the FDA concerning AMPLIFY months earlier, and that Wells Fargo considered an expected settlement with the DOJ concerning INFUSE off-label promotions a considerable risk:

AMPLIFY Non-Approvable Letter Puts InFuse Sales At Risk:

Summary: MDT’s FQ3 2011 10-Q, which was issued after the close today (3/9), indicated that MDT received a non-approvable letter from the FDA in FQ3 2011 (November 2010-January 2011) for its bone graft product AMPLIFY.

* * *

In addition to the non-approvable letter for AMPLIFY, we see additional downside risk for InFuse due to a likely settlement with the DOJ on the off-label promotion of InFuse and increasing competition.

81. On March 10, 2011, Wedbush issued a report titled “No Surprise in FDA’s ‘No’ to Amplify – The Real Issues are Ongoing Weakness in Spine Market, Unrealistic Street Expectations for FY 2012.” The March 10, 2011 report also explained that the

⁵ The March 9, 2011 Form 10-Q included false Sarbanes-Oxley certifications of Hawkins and Ellis in substantially identical form as those attached to the September 28, 2010 and December 8, 2010 Forms 10-Q.

disclosure in the Form 10-Q that AMPLIFY was not approved was not a surprise and that likelihood had already been built into the Company's pricing models with the assumption that the Company's spine business would be flat or decline 1.5%. The report noted, however, that some investors still expected AMPLIFY would revitalize the biologics:

FDA declines to approve expanded label for MDT's spine fusion biologic:

* * *

The rejection of Amplify was already built into our models. . . . ***But many investors had been clinging to the hope that an approval of Amplify*** would help MDT to revitalize its biologics business and its broader spine surgery franchise.

82. The March 9, 2011 Form 10-Q – which for the first time revealed the non-approvable letter concerning AMPLIFY of which defendants had actual knowledge, but failed to disclose prior to February 22, 2011 – caused the Company's stock price to decline from a close of \$39.80 on March 9, 2011, to a close of \$38.63 on March 10, 2011.

83. On April 11, 2011, *The New York Times* published an article titled “Medtronic Bone-Growth Product Scrutinized.” The article discussed the widening DOJ investigation and stated that doctors who performed research studies on behalf of Medtronic were also being paid millions in consulting fees. The article detailed that one doctor, Dr. Timothy Kuklo, had overstated INFUSE benefits in a medical journal. The article did not, however, report what would later be revealed – that Medtronic and its employees for many years routinely participated in the editing and drafting of medical articles (which doctors and the public relied upon for their integrity) that failed to disclose known adverse side effects. Indeed, it would later be disclosed that Medtronic influenced content purportedly authored by doctors who were reporting on the clinical results of trials of INFUSE. Nor did *The New*

York Times article disclose that the same doctors were paid millions to conceal, or significantly downplay, known adverse events that occurred in INFUSE clinical trials:

One of Medtronic's most profitable divisions—selling bone growth products used in spinal fusion procedures—faces growing pressure amid a widening criminal investigation *into the company's marketing* of one product and a rejection by federal regulators of another one.

Recently, the Food and Drug Administration turned down the company's application to sell a new spinal fusion device that is essentially a high-strength version of an approved one called Infuse.

* * *

Prosecutors have also sought records from United States Army researchers involved in studies of Infuse

* * *

The Army's 2008 report on that investigation found that a former military doctor, Dr. Timothy R. Kuklo, had overstated Infuse's benefit in a medical journal study that examined its use in the treatment of soldiers

Dr. Kuklo, who became a Medtronic consultant, also forged the signatures of that study's co-authors in a journal submittal, the Army said. Medtronic later broke its ties to him, and the medical journal that published the article retracted it.

* * *

In 2002, the Food and Drug Administration approved the use of Infuse for a certain type of spinal fusion procedure, in which problem spinal vertebrae are joined in an effort to stop severe back pain. . . .

Some of the doctors who performed research studies into such so-called *off-label* uses of Infuse received millions of dollars in consulting fees from Medtronic.

84. Notwithstanding the rejection of AMPLIFY, and the other adverse news described above, on May 18, 2011, Medtronic stock reached its Class-Period high of \$43.20 per share.

85. On May 24, 2011, before trading opened on the NYSE, Medtronic issued a press release announcing its 4Q11 and FY11 financial results. The Company reported earnings of \$3.096 billion, or \$2.86 diluted EPS, and revenue of \$15.933 billion for FY11. The Company's 4Q11 EPS results missed Wall Street analysts' consensus EPS forecasts, reporting earnings of \$776 million, or \$0.72 diluted EPS, and revenue of \$4.295 billion. Later the same day, May 24, 2011, Medtronic held a conference call for analysts and investors to discuss the results. The conference call was hosted by Ellis and the Company's Vice President of Investor Relations, Jeff Warren. During the conference call, the Company, and specifically Ellis, falsely stated that the Company set high standards for quality in the industry:

[ELLIS:] In the U.S., we resolved all 3 warning letters and we continue to focus on meaningful quality improvement. ***Medtronic continues to set the standard for quality in the industry.***

86. By the end of the day, May 24, 2011, Medtronic stock had traded 14.9 million shares and closed at \$40.88, down from a close of \$41.26 on May 23, 2011.

87. Reasons Why the Statements in ¶¶70-73, 78, 85 Were Materially and Knowingly False and Misleading. Each of the representations set forth in ¶¶70-73, 78, 85 concerning (i) the design of clinical studies purportedly showing the safety and efficacy of Medtronic's therapies and products, including INFUSE; (ii) the sufficiency and effectiveness of the Company's internal controls to uncover fraud; and (iii) the Company setting the standard for quality in the industry, were each materially false and misleading and served to further the Company's fraudulent scheme and course of conduct to conceal the true facts about INFUSE and AMPLIFY including the risk of the impact the truth would have on the

Company's financial condition. In truth, defendants knew but failed to disclose the following facts which, once revealed, caused economic loss to investors in Medtronic stock during the Class Period:

(a) First, Medtronic did **not** "set the standard for quality in the industry," and did **not** engage in well-planned studies showing the safety and efficacy of INFUSE or AMPLIFY. Instead, Medtronic heavily edited and influenced the publication of medical journal articles that intentionally omitted or understated the significant side effects and adverse events associated with INFUSE. For years, Medtronic and its employees or agents drafted, or participated in the drafting of, purported physician-authored articles that were published in medical journals relating to the clinical trials for INFUSE. Indeed, in one instance, Burkus, a highly-paid Medtronic consultant and "author" of several INFUSE-related articles, admitted that for the 2002 article titled "Clinical and Radiographic Outcomes of Anterior Lumbar Interbody Fusion on Recombinant Human Bone Morphogenic Protein-2," he could "take credit for only a small fraction of the work that ha[d] gone into this paper," referencing the significant input Medtronic employees had in its creation. Ex. D.⁶ Each of the early articles was published without attributing the writings to Medtronic or indicating that Medtronic had been materially involved in editing or drafting the articles or fully disclosing the financial ties between the doctors and Medtronic.

(b) Specifically, defendants knew, but failed to disclose, that Medtronic and its executives and employees participated in drafting or editing the following articles that

⁶ In a separate communication, Burkus stated that even his colleagues, who were named as his co-authors on an INFUSE article, "did not write one word." See Ex. E.

nearly all, if not all, failed to disclose adverse events known to or recklessly disregarded by Medtronic and the author physicians:

- 2002. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. *J. Spinal Disord. Tech.* 2002; 15:337- 49.
- 2002. Burkus JK, Transfeldt EE, Kitchel SH, et al. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein-2. *Spine J.* 2002.
- 2003. Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT-CAGE lumbar tapered fusion device. *J. Spinal Disord. Tech.* 2003.
- 2003. Baskin DS, Ryan P, Sonntag V, et al. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein- 2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate. *Spine J.* 2003.
- 2003. Burkus JK, Dorchak JD, Sanders DL. Radiographic assessment of interbody fusion using recombinant human bone morphogenetic protein type 2. *Spine J.* 2003.
- 2004. Haid RW, Branch CL, Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. *Spine J.* 2004.
- 2005. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP- 2 in combination with structural cortical allografts surgery: clinical and radiographic outcomes in anterior lumbar spinal fusion. *J. Bone Joint Surg. Am.* 2005; 87:1205-12.
- 2007. Glassman SD, Dimar JR, Burkus K, et al. The efficacy of rhBMP-2 for posterolateral lumbar fusion in smokers. *Spine J.* 2007.
- 2009. Dimar JR, Glassman SD, Burkus JK, et al. Clinical and radiographic analysis of an optimized rhBMP-2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. *J. Bone Joint Surg. Am.* 2009.
- 2009. Burkus JK, Gornet MF. Six-Year Outcomes of Anterior Lumbar Interbody Arthrodesis with Use of Interbody Fusion Cages and Recombinant Human Bone Morphogenetic Protein-2. *J. Bone Joint Surg. Am.* 2009.

- 2009. Dawson E, Bae HW, Burkus JK, et al. Recombinant human bone morphogenetic protein-2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial. *J. Bone Joint Surg. Am.* 2009.

(c) Medtronic and the Individual Defendants also knew, but failed to disclose, that between 1996 and 2010, Medtronic had paid a staggering **\$210 million** to physician authors who published the above-mentioned medical literature concerning INFUSE, and that such payments, and Medtronic's involvement in the drafting and editing of these articles, were part of and/or advanced an undisclosed scheme to conceal or materially minimize adverse events observed during clinical trials of INFUSE and related treatments containing rhBMP-2. Each of these published articles purported to discuss the benefits of INFUSE while omitting adverse medical side effects of its usage, including, but not limited to, retrograde ejaculation, osteolysis, bone cyst formation and neurological complications. In addition, the published literature failed to acknowledge or identify adverse events that were known to both the authors and to defendants to be associated with the use of INFUSE.

(d) Defendants knew, but failed to disclose, their participation in this fraudulent scheme, and the undue influence they exerted over the published literature regarding INFUSE. Even as government investigators, media observers and investors sought information concerning financial ties to physicians who used INFUSE or promoted off-label use of INFUSE, Medtronic and its employees and agents, while purporting to cooperate with such requests for information, were not in fact cooperating. In truth, defendants continued to conceal that, among other things, the initial medical journal literature that reported efficacy,

claims that INFUSE caused no adverse side effect, and the reports of safety of INFUSE and INFUSE-related treatments, were truly a result of the undisclosed scheme, including the intentional omission by defendants and their agents of adverse events associated with INFUSE.

(e) The Company knew, but disregarded and failed to disclose, that revenues and profits in connection with the spine unit (and particularly, biologics) had historically been driven, not by the safety and efficacy of the treatments, but by defendants' fraudulent scheme and intentional concealment of the true side effects of INFUSE. Specifically, defendants and their agents concealed or caused to be concealed the true and biased design of clinical studies of INFUSE, known adverse events and side effects associated with INFUSE observed during those trials, and that Medtronic paid tens of millions of dollars to physicians who knew but failed to disclose these same facts. Further, the potential approval and resulting sales growth of AMPLIFY was based upon the initial and continued concealment of the known adverse events and risks that Medtronic either removed or scrubbed from literature concerning INFUSE.

(f) Defendants knew, but failed to disclose, that the design of clinical trials and/or reporting of the results of clinical trials in connection with INFUSE and related treatments, including AMPLIFY, were not designed to show its safety and efficacy, but to obscure and conceal known harmful side effects of INFUSE, such as to avoid the stoppage of clinical studies and detection of its harmful effects. In addition to paying physician authors to conceal adverse events during clinical trials and drafting and editing the articles without disclosing Medtronic's participation therein, a 2006 e-mail written by Yahiro, a Medtronic

Senior Director of Regulatory Affairs, plainly demonstrates that the Company's efforts to convince the FDA to loosen rules regarding the disclosure of adverse events were driven by a desire to obscure adverse events associated with INFUSE and INFUSE-related products, specifically AMPLIFY. The e-mail indisputably evidences defendants' intent and advancement of the scheme and course of conduct designed to obscure the true facts concerning the efficacy and safety of INFUSE and INFUSE-related treatments. In connection with an FDA rule change proposed by Medtronic, Yahiro explained to his colleagues that Medtronic's proposal was written the way it was so that it would be difficult to "pin" the cause of an adverse event on INFUSE:

Thanks for your note. I think we're all on the same page regarding the ability to determine the exact cause of an event that could possibly be related to INFUSE (or just a result of cervical surgery). ***We agree it would be difficult to pin it on INFUSE, which is exactly why we wrote the stopping rule that way. What we don't want is a rule that would have specific events with incidence rates, etc., that would stop the trial when it would be hard to say it WASN'T INFUSE.***

The way we wrote it, WE make the determination whether it was INFUSE-related. This way, if a patient has an AE like severe cervical swelling, we can honestly say that it is not possible to know that the cause is definitely INFUSE and therefore the study need not be stopped.

Ex. C at 17-18.

(g) Defendants further knew, but failed to disclose, that the clinical studies of INFUSE and related treatments were designed not to elicit information about serious adverse events, but instead were often biased in favor of INFUSE, thereby falsely and artificially reflecting lower numbers of adverse events than in fact existed. One independent review of Medtronic's clinical studies, protocols and data, published in 2013, showed that:

For harms, the studies used broad classifications for many adverse events, and *events were generally not actively elicited* by means of specific symptom questionnaires or objective tests. . . . *Cancer was not a prespecified endpoint and was only captured by voluntary reporting.*

(h) Likewise, a later independent review of Medtronic's study protocols shows that the clinical studies for INFUSE and related treatments were not designed to elicit information about possible adverse events, including retrograde ejaculation, which was not clearly defined; it was also not clear "whether investigators asked about specific symptoms" that would lead to an accurate diagnosis and reporting of retrograde ejaculation as an adverse event. Similarly, defendants knew that in June 2004, in reviewing an article that was ultimately published in the *Journal of Bone & Joint Surgery*, Bearcroft advised that a study to be published by Burkus not include any "significant detail" on adverse events: "I personally think it is appropriate to simply report the adverse events were equivalent in the two groups without the detail." *See* Ex. C. The Senate Report revealed that, as a result of Bearcroft's advice, a table summarizing the adverse events seen in the trial was removed from the draft, and the published paper reported no complications. *Id.*

(i) Defendants also knew, but failed to disclose, that the current and future sales growth of INFUSE and related treatments were dependent upon continued concealment of defendants' role and direct participation in doctor communications to the medical professional community and their undisclosed efforts to suppress the truth about adverse effects of INFUSE, including retrograde ejaculation and cervical swelling. The Senate Report exhibits confirm that as early as 2004, Medtronic was receiving complaints about severe swelling in cases where INFUSE was used in the cervical spine, and that Medtronic

had begun analyzing whether there was a causal association between INFUSE and these events. In April 2004, Trehearne tried to convince Boden with an analysis that purported to show the ***lack*** of such causal relationship. But Boden remained unconvinced, as revealed in the following e-mail:

While statistically your numbers do not suggest an increased incidence, ***I think there is a possibility that could be a misleading conclusion.***

* * *

At this point, the statistics do not prove anything one way or another, but ***I am still concerned that there could be an association between BMP-2 and edema in these cervical cases. . . . I think continued warning needs to be advised to surgeons*** about off-label use, especially in the cervical spine.

Ex. F.

(j) According to the Senate Report, by August 2004, in response to an inquiry from the North American Spine Society whether the organization should caution doctors against using INFUSE in the cervical spine, Boden stated, “it may be premature for an ‘official warning.’” Ex. C. A strong inference of intentional conduct is warranted from the fact that Medtronic’s consulting fees to Boden catapulted from \$704,000 through 2004 to ***over \$28 million*** by the end of 2008. It would be reported later that there were significant complications, some serious, in connection with the use of INFUSE in the cervical spine. In fact, based on an independent review of Medtronic’s data, two prominent spine surgeons stated that INFUSE should not be used in cervical procedures absent a compelling reason.

(k) Defendants likewise knew, but failed to disclose, that the design, protocols, and published results of clinical trials of INFUSE and related treatments did not demonstrate INFUSE’s superiority over alternative procedures but instead such superior

results were artificially manufactured. For example, a published study claimed that INFUSE achieved superior fusion results compared with the use of the LT-Cage alone, but an internal Medtronic report acknowledged the difference in fusion rates was likely a result of the physicians who treated the non-INFUSE patients lacking experience in the particular procedure studied. The published results of this study did not disclose this fact and indeed a later Medtronic-supported article expressly disclaimed any difference in surgical experience between the control and test groups. Similarly, another Medtronic-supported study reported that INFUSE patients had no donor-side hip pain, when in reality the INFUSE patients were never assessed for hip pain, only the control-group patients.

THE TRUTH ABOUT DEFENDANTS' FRAUDULENT SCHEME AND FALSE AND MISLEADING STATEMENTS BEGINS TO EMERGE

88. The truth about defendants' ongoing scheme and the false and misleading statements during the Class Period – that because of Medtronic's improper influence over clinical researchers, the published medical literature in support of INFUSE's efficacy, safety, and superiority over alternative procedures was wholly unreliable – was revealed in a series of partial disclosures. However, even as the truth began to be more fully revealed, the Company and Zdeblick continued to issue additional knowingly false and misleading statements.

The May 25, 2011 *The Spine Journal* Articles

89. On May 25, 2011, shortly after midnight, *The Spine Journal* published a clinical study titled "Retrograde Ejaculation After Anterior Lumbar Interbody Fusion Using

rhBMP-2: A Cohort Controlled Study.”⁷ Ex. G. By retrospectively analyzing data from spinal fusion patients over a period of 3 years, the researchers determined there was a 7.2% incidence of retrograde ejaculation in INFUSE patients, compared with 0.6% incidence in those patients who did not receive INFUSE. *Id.*

90. A related commentary published by *The Spine Journal* on the same day titled “Another Complication Associated with rhBMP-2?” by James D. Kang, questioned the risks of male infertility disclosed in industry-sponsored publications regarding INFUSE, finding higher incidence of retrograde ejaculation in male patients using INFUSE. Ex. B. The author concluded that industry-sponsored denials of a link between retrograde ejaculation and INFUSE were “not credible.” *Id.*

91. Also on May 25, 2011, *Bloomberg* published an article titled “Medtronic’s Infuse Bone Product Raises Risk of Male Infertility,” discussing *The Spine Journal* study. The *Bloomberg* article explained that while there were early questions about the connection between INFUSE and infertility, the Company-sponsored studies never even mentioned the known risks. Troublingly, newer, non-Company sponsored studies showed that the risk of such side effects was in fact significant and that more than 7% of patients in a new study of those who used INFUSE developed retrograde ejaculation compared to only 0.6% who did not use INFUSE:

⁷ The study was conducted by: Eugene J. Carragee, MD, Kyle A. Mitsunaga, MD, Eric L. Hurwitz, DC, PhD and Gaetano J. Scuderi, MD.

Medtronic's Infuse Bone Product Raises Risk of Male Infertility

Medtronic Inc.'s Infuse, a genetically engineered protein used to spur the growth of new bone after spinal surgery, increases the risk of infertility in men following some operations, researchers said.

... Studies funded by Minneapolis-based Medtronic didn't mention the side effect, and the clean safety profile led doctors to embrace the therapy that can eliminate painful harvesting of bone or reduce the need for screws and plates, he said.

The study published in the June issue of *The Spine Journal* found 7.2 percent of Carragee's patients treated with Infuse during spine surgery developed retrograde ejaculation, when semen is misdirected into the bladder, compared with 0.6 percent of those who didn't get the product.

92. Similarly, on the morning of May 25, 2011, *The New York Times* published an article titled "New Study Links Spine Product from Medtronic to Male Sterility." The article described *The Spine Journal's* findings in layman's parlance, including that among 240 patients that Dr. Carragee tracked, 69 were given INFUSE and 174 were not. The report indicated that 5 out of the 69 who received INFUSE developed retrograde ejaculation and only 1 of the 174 patients not given INFUSE developed retrograde ejaculation. *The New York Times* article also noted that Burkus and Zdeblick, who were involved in the initial clinical trials of INFUSE, and wrote the key early articles, never mentioned the complication in their research literature before INFUSE was approved by the FDA; in later reports they attributed the complication to a particular surgical technique as opposed to INFUSE:⁸

New Study Links Spine Product From Medtronic to Risk of Sterility in Men

A surgeon at Stanford University, in a study released Wednesday, suggests that one of Medtronic's best-selling spinal products poses a risk of

⁸ 2002. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. *J. Spinal Disord. Tech.* 2002; 15:337-49.

male sterility. ***That finding is in stark contrast to earlier research by doctors paid by Medtronic, who found no connection between the product, Infuse, and a condition that causes sterility.***

... The Infuse label notes the sterility-related complication as a possible side effect, ***but the Medtronic-sponsored researchers in published reports attributed that complication to surgical technique, not the product itself.***

* * *

Among the 69 patients treated by Dr. Carragee who received Infuse, five men developed the complication related to sterility, ***in contrast to one patient among the 174 men who received a bone graft.***

93. The May 25, 2011 *The New York Times* article also published a response sent from Zdeblick by e-mail to the questions and criticisms raised by the May 25, 2011 *The Spine Journal* article. Zdeblick's response, which he knew would be published, served to further defendants' fraudulent scheme by suggesting that it was in fact Carragee's new May 25 study that was "misleading" and of limited value. The article also noted that certain doctors, including Zdeblick, had received millions in consulting fees from Medtronic:

In an e-mail, Dr. Zdeblick said Dr. Carragee's study was of limited value because it reflected the results of a retrospective look at patients rather than a clinical trial. Such reports "***are notorious for being misleading,***" he wrote.

* * *

Both men have adamantly insisted that those financial relationships have not affected their scientific judgment.

* * *

Since 2006, an orthopedic surgeon in Croatia, Dr. Tomislav Smoljanovic, has written more than 35 letters to medical journals questioning the claims. ***In their 2002 report, Dr. Burkus and Dr. Zdeblick reported that a major clinical study involving Infuse had found no adverse effects with the product, including the sterility-related complication.***

Among other things, Dr. Smoljanovic and colleagues pointed out in letters that the ***Medtronic-sponsored researchers, while identifying that six men in their study had developed the sterility-related complication, had not identified how many of those men had received Infuse as opposed to a bone graft.***

Last year, Dr. Burkus and his colleagues publicly disclosed in response to the Croatian physicians' letters that five of the six men affected in their study had received Infuse. ***However, they have insisted that the figure was not statistically significant to link the problem with Infuse.***

94. Securities analysts soon picked up on these studies and articles. Later that same day, May 25, 2011, Collins Stewart LLC ("Collins Stewart") issued a report titled "New Adverse Event with Infuse Could Create Another Headwind," and again discussed *The Spine Journal*'s findings indicating this new information and greater awareness of these risks could significantly reduce sales:

A potential link between InFuse and male sterility might dampen sales.

... In this retrospective study of male patients (69 with InFuse; 174 without), the rate of retrograde ejaculation was 7.2% with InFuse and 0.6% without.

... We believe that greater awareness of the association of retrograde ejaculation with InFuse could significantly reduce InFuse sales. We estimate that every \$100 million reduction in InFuse sales represents approximately 3-4c of EPS. We are leaving our estimates unchanged as we dig further into the new data.

95. Following the disclosure of the May 25, 2011 *The Spine Journal, Bloomberg*, and *The New York Times* articles reporting on the "not widely-known" fact that INFUSE could cause retrograde ejaculation, the Company's stock price declined from a close of \$40.88 on May 24, 2011, to a close of \$40.23 on May 25, 2011.

96. Simultaneous with the May 25, 2011 publication of the Carragee study and related news reports, Medtronic admitted that it knew of the infertility risks in the original

studies but falsely claimed they were not statistically significant. For example, the *Minnesota Star Tribune* discussed *The Spine Journal*'s findings in an article titled "Study Links Medtronic Product to Sterility Risk." The article also quoted Medtronic officials and doctors who had written and published medical journal articles that had previously failed to disclose the risks associated with INFUSE:

A study released by a medical journal Wednesday suggests that a bone-growth product that Medtronic Inc. markets for back surgery may lead to increased risk of sterility in men.

The study, published in the June issue of the Spine Journal, analyzed 243 patients who underwent some types of back surgery and found that those treated with the Medtronic product experienced higher rates of temporary and permanent sterility.

* * *

Medtronic spokeswoman Marybeth Thorsgaard said in a statement that in the original study that supported FDA approval of Infuse, infertility problems were not common enough to be statistically linked to the product.

97. The *Minneapolis Star Tribune* also reported that Zdeblick wrote an e-mail response to the reports which falsely suggested that it was in fact Carragee's study that was flawed and misleading:

In an e-mail statement, Zdeblick said the study was "interesting, [but] a single publication in the medical literature does not constitute a 'truth'. Retrospective trials are notorious for being misleading."

Zdeblick said Carragee's study has "numerous flaws," but his findings are nonetheless in line with other Infuse studies.

98. While the May 25, 2011 disclosure caused the Company's stock price to suffer material decline, defendants' knowingly false denials caused the stock to continue to trade at artificially inflated levels.

99. Reasons Why Statements in ¶¶93, 96, 97 Were False and Misleading.

Defendants knew that the Company statements in ¶¶93, 96, 97 concerning the lack of statistically significant evidence of INFUSE's association with retrograde ejaculation were false. Notwithstanding the Company's denial that incidence of retrograde ejaculation among INFUSE patients was statistically different or statistically significant, and Zdeblick's statement to reporters that Carragee's study was flawed and misleading, the Senate Report showed that Medtronic and Zdeblick knew as early as **2001** that retrograde ejaculation rates were higher in both investigational groups (*i.e.*, INFUSE patients) than the control group. In a PowerPoint presentation made to study investigators in February 2001, Zdeblick reported that among INFUSE patients, there was a 10.3% rate of retrograde ejaculation using the laparoscopic technique, and a 6.3% rate for patients who underwent an "open" technique, compared to a 1.5% rate for the control group. The 10.3% rate was noted in the presentation to be "*[s]tatically different from [the] control [group]*":

**InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered
Fusion Device
IDE G960065 – Pivotal Trial Results**

Adverse Events (%)

Anatomical/Technical Difficulties	Investigational		Control 1.5
	Open 0.0	Laparoscopic 7.4*	
Back/Leg Pain	16.6	15.4	12.5
Gastrointestinal	17.9	9.6	11.8
Infection	7.6	10.3	6.6
Neurological	7.6	8.8	10.3
Retrograde Ejaculation	6.3	10.3*	1.5
Spinal Event	8.3	2.9	8.1
Subsidence	2.8	0.7	0.0
Trauma	13.1	14.0	16.9

*Statistically different from control

100. Later, Zdeblick would admit that this finding should have been mentioned in the Company's report about the initial trial of INFUSE in the *Journal of Spinal Disorders* in 2002, but maintained that the risk of sterility linked to INFUSE wasn't reported in journal articles because it wasn't statistically significant.

101. On June 21, 2011, the Senate Finance Committee sent a letter to Medtronic, which was made public by the Committee the next day, identifying concerns regarding relationships with physician authors and their knowledge of dangerous side effects connected to the usage of INFUSE and the failure to disclose those side effects in peer-reviewed journal articles. These inquiries from the Senate Finance Committee had become almost routine over the prior several years (*see ¶¶67 n.4, 68*); therefore, investors' reaction to the request was muted. However, it was clear from the June 21, 2011 request for information that the scope of the Committee's prior inquiries in 2007 and 2008, which sought information concerning financial ties from 2007 forward, did not contemplate that the doctors responsible for the initial clinical trials were aware of adverse events but failed to report them in medical literature because Medtronic was paying them massive consulting fees in order to influence their conclusions and findings:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs.

We are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of Infuse on behalf of Medtronic were aware that Infuse, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to Medtronic.

Last year, the *Milwaukee Journal Sentinel* reported that a Medtronic-funded study published in 2004 found that 75% of bone morphogenetic protein

2 (BMP-2) patients experienced ectopic bone growth, where potentially harmful bone growth occurs outside of the fusion area. The authors, who had financial ties to Medtronic, “concluded that ‘although not desirable,’” the ectopic bone growth “did not appear to have an ill effect on the patients.” However, in a separate 2008 study conducted by physicians without financial ties to Medtronic, “neurological impairment occurred” in five patients who had the same ectopic bone formation.

According to the New York Times, a recent study “found that men treated with Infuse developed a condition that causes temporary or permanent sterility at a far higher rate than men who received a bone graft.” *This link to sterility was not reported in the original Medtronic-funded study. In addition, the Milwaukee Sentinel Journal reports that one author of the original study, Thomas A. Zdeblick, an orthopedic surgeon at the University of Wisconsin School of Medicine and Public Health, received “more than \$23 million in various royalty payments from Medtronic since 2002.”* In addition, *“Zdeblick also is the editor of the journal where two of the Infuse papers that failed to mention the link [to sterility] were published.”*

102. On June 23, 2011, Medtronic issued a press release regarding the INFUSE product and the inquiry from Senator Grassley, which stated in part:

We are in receipt of an inquiry from Senators Grassley and Baucus requesting information related to our INFUSE® Bone Graft product and intend to respond. Additionally, it is important to emphasize that the three adverse events highlighted in the letter are already listed as warnings on our FDA approved product labeling for INFUSE® Bone Graft. Furthermore, patient safety is of the utmost important [sic] to Medtronic. Accordingly, we provide PMA clinical study adverse event data to the FDA irrespective of any financial relationship between the company and the clinical investigator or study author.

The June 28, 2011 *The Spine Journal* Articles

103. On June 28, 2011, *The Spine Journal* devoted an entire issue to the INFUSE product, including the conflicts of interest by researchers who had performed studies on INFUSE and the underappreciated risks and side effects associated with INFUSE. To dedicate an entire issue of a journal to such topics was unprecedented in medical literature and underscored the serious and startling conclusions that the journal’s authors and editors

had made. As expressed by five doctors who wrote the editorial that prefaced the journal articles: “It harms patients to have ***biased and corrupted research*** published. It harms patients to have unaccountable special interests permeate medical research. It harms patients when poor publication practices become business as usual.” Ex. H at 466. Taken as a whole, the June 28, 2011 issue of *The Spine Journal* began to inform the market, for the first time, that the research supporting the safety and efficacy of INFUSE was not reliable.

104. The June 28, 2011 *The Spine Journal* article, Critical Review, focused on the original “peer reviewed . . . industry-sponsored publications” describing rhBMP-2 and noted specifically that adverse events experienced by patients in the years following the approval of INFUSE were not reported “at all” in the early industry-sponsored publications, nor was it reported that adverse events were associated or connected to rhBMP-2. Ex. A at 474, 478. In addition, the Critical Review noted that the study design for the industry-sponsored trials had the potential for methodological bias and in some cases, serious potential design bias. Finally, the article revealed that the financial ties of physician authors to Medtronic were massive and had not been fully disclosed:

RESULTS: There were 13 original industry-sponsored rhBMP-2 publications regarding safety and efficacy, including reports and analyses of 780 patients receiving rhBMP-2 within prospective controlled study protocols. ***No rhBMP-2-associated adverse events (0%) were reported in any of these studies (99% confidence interval of adverse event rate <0.5%).***

The study designs of the industry sponsored rhBMP-2 trials for use in posterolateral fusions and posterior lateral interbody fusion were found to have potential methodological bias against the control group.

The reported morbidity of iliac crest donor site pain was also found to have serious potential design bias. Comparative review of FDA documents and subsequent publications revealed originally unpublished adverse events and internal inconsistencies. From this review, ***we suggest an estimate of adverse***

events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach. Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including life-threatening events.

After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. Posterior lumbar interbody fusion use was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. ***In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects*** reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy.

Id. at 471-72.

105. The Critical Review also included a chart of each of the thirteen early industry-sponsored rhBMP-2 clinical studies which were drafted by the authors who failed to report adverse events rates:

Table 1

Original industry-sponsored rhBMP-2 clinical studies and reported adverse event rates because of rhBMP-2

Authors	rhBMP-2 Placement	rhBMP-2, n	rhBMP-2 Adverse events (%)	Authors comments regarding rhBMP-2 related observed adverse events in study patients
Boden et al. [2]	Anterior interbody (LT-cage, lumbar, rhBMP-2)	11	0	“There were no adverse events related to the rhBMP-2 treatment”
Boden et al. [3]	Posterolateral (lumbar, ± instrumentation)	20	0	“There were no adverse effects directly related to the rhBMP-2...”
Burkus et al. [5]	Anterior interbody (LT-cage, lumbar, INFUSE)	143*	0	“There were no unanticipated device-related adverse events...”
Burkus et al. [6]	Anterior interbody (bone dowel, lumbar, INFUSE)	[24] [±]	0	“There were no unanticipated adverse events related to the use of INFUSE Bone Graft.” (2002)
Burkus et al. [39]		79	0	None reported (2005)
Burkus et al. [40]	Anterior interbody (LT-cage, lumbar, INFUSE)	277	0	None reported
Baskin et al. [7]	Anterior interbody (cervical, INFUSE)	18	0	“There were no device-related adverse events”
Haid et al. [8]	Posterior interbody fusion (lumbar, INFUSE)	34	0	“No unanticipated device-related adverse events occurred”
Boakye et al [41]	Anterior interbody (cervical, INFUSE)	24	0	“Analysis of our results demonstrated the safety and efficacy of this combination of cervical spine fusion therapy a 100% fusion rate and nonsignificant morbidity”
Dimar et al. (2009)	Posterolateral (lumbar, INFUSE, pedicle screws)	53	0	None reported
Glassman et al. [42]	Posterolateral (lumbar, AMPLIFY, and pedicle screws)	[148] [±]	0	None reported
Dimar et al. [10]	Posterolateral (lumbar, AMPLIFY, and	239	0	“No adverse event that was specifically

Table 1

Original industry-sponsored rhBMP-2 clinical studies and reported adverse event rates because of rhBMP-2

Authors	rhBMP-2 Placement	rhBMP-2, n	rhBMP-2 Adverse events (%)	Authors comments regarding rhBMP-2– related observed adverse events in study patients
	pedicle screws)			attributed to the use of rhBMP-2 matrix in the study group was identified”
Dawson et al. [11]	Posterolateral (lumbar, INFUSE, and pedicle screws)	25	0	None reported
Total	All types	780	0	99% CI < 0.5% adverse event rate

Id. at 473.

106. The Critical Review added that for 12 of the 13 studies, the Company had massive financial relationships with the doctors who authored the studies:

As of March 2011, of the 13 original studies, there was one study with no information available regarding the authors[’] financial relationship with the rhBMP-2 manufacturer. *Of the remaining 12 studies, the median-known financial association between the authors and Medtronic Inc. was found to be approximately \$12,000,000–\$16,000,000 per study (range, \$560,000 – \$23,500,000).*

Id. at 475.

107. Further still, the June 28, 2011 articles in *The Spine Journal*, specifically “Iliac Crest Bone Graft: Are the Complications Overrated?”, suggested that pain associated with ICBG had been greatly overstated by the authors of industry-sponsored studies. Ex. I. In fact, in a clinical study of post-spine-fusion patients in which both the patient and the examiner were unaware of whether bone had been harvested from the patient’s iliac crest, researchers found that “[w]hether or not bone graft was actually harvested, 54% of patients complained of tenderness over the iliac crest, with the majority having tenderness over both crests rather than either one.” Ex. J at 536. These study results were published in the June 28, 2011 issue of *The Spine Journal* in an article titled “Posterior Iliac Crest Pain After Posterolateral Fusion with or Without Iliac Crest Graft Harvest.” Ex. J. The Senate Report

would later confirm that the Company and its executives specifically sought to emphasize pain associated with alternative techniques:

Documents show that Medtronic edited draft publications to stress the pain patients experienced from undergoing a bone graft procedure instead of receiving InFuse.

* * *

After receiving a draft of an early InFuse study to review in October 2001, Medtronic's Neil Beals, whose "primary job responsibility was to manage Biologics marketing programs and initiatives," ***recommended that the physician authors of the study emphasize pain experienced by patients who received the bone graft.*** The patients were divided into an investigative group that received InFuse and a control group that received a bone graft obtained from the iliac crest of their pelvis. An October 31, 2001 e-mail shows that ***Beals suggested to Dr. Burkus that "a bigger deal should be made of elimination of donor site pain with INFUSE . . . so that 'equivalent' results aren't received as a let down."***

See Ex. C at 11.

108. In a separate commentary in the June 28, 2011 edition of *The Spine Journal* titled "Folly of FDA-Approval Studies for Bone Morphogenetic Protein," Dr. Sohail Mirza detailed that, in order to generate positive clinical study data that would allow INFUSE to become the standard of care, Medtronic designed studies in such a way that they were biased against the control group, stating "the 13 seminal publications [in support of INFUSE] ***systematically aligned research factors to favor results for BMP.***" Ex. K at 495. Specifically, Dr. Mirza detailed that the Medtronic-sponsored studies were biased in favor of INFUSE because: (i) they were open-label, introducing investigator bias; (ii) they were designed as non-inferiority studies, so there was no requirement to show superior efficacy to alternatives; (iii) rhBMP-2 was classified as a medical device rather than a drug, the former having a less rigorous approval process; (iv) the control treatment was not delivered

optimally, compromising efficacy results; (v) adverse events for the treatment groups were underreported; (vi) complications in the control group were overreported; and (vii) the researchers had conflicts of interest due to their financial relationships with Medtronic. *Id.* at 495-99 (fig. 1).

109. On the same day, June 28, 2011, in response to the articles in *The Spine Journal*, Medtronic issued a press release that stated in part:

Following is a statement from Omar Ishrak, chairman and chief executive officer of Medtronic, Inc. on a series of articles on recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) published in a recent edition of *Spine Journal*.

“Integrity and patient safety are **my** highest priorities. While the *Spine Journal* articles raise questions about researchers’ conclusions in their published peer-reviewed literature, the articles do not raise questions about the data Medtronic submitted to the FDA in the approval process or the information available to physicians today through the instructions for use brochure attached to each product sold.

110. On June 29, 2011, J.P. Morgan issued a report titled “Infuse in the Crosshairs; Lowering Estimates.” The report discussed in detail the June 28, 2011 after-hours publication of *The Spine Journal* articles concerning the Company’s improper relationships with physician authors and their financial ties to Medtronic. The J.P. Morgan report also discussed the negative impact of these “unprecedented” disclosures – including Carragee’s findings that adverse events were 10 to 50 times higher than initially reported – would have on the Company’s sales going forward and ultimately its share price:

Infuse in the Crosshairs; Lowering Estimates

Tuesday after the close, *The Spine Journal* released a scathing criticism of Medtronic’s Infuse. In an entire issue dedicated to the subject, the editors asserted (1) **systematic underreporting of adverse events in the clinical studies supporting Infuse’s US approval**, (2) **faulty trials designs**, and (3)

widespread [undisclosed] financial conflicts of interest among the surgeons who participated in the studies and reported the results. While Infuse has been no stranger to controversy over the years and Medtronic is publicly standing behind the validity of its research, ***we believe that this heightened level of scrutiny has the potential to significantly impact its utilization. . . .***

... In aggregate, the articles represent an unprecedented attack on ***the quality of the research used to support Infuse's approval***, raising serious questions about a wide variety of issues

* * *

Carragee asserts that “authors of nearly all those trials had financial ties with the manufacturer of rhBMP-2, with various compensations ranging to more than \$26M/per study.”

111. On the same day, June 29, 2011, Collins Stewart issued a report titled “Spine Journal Focuses Negative Spotlight on InFuse (Again).” In addition to highlighting *The Spine Journal*’s analysis of previously issued articles, which had not fully disclosed INFUSE-related adverse events, the Collins Stewart report projected the negative impact of the reports on future sales:

The latest issue of the Spine Journal focuses on adverse events related to Medtronic’s InFuse and are likely to further dampen sales. The latest issue of the Spine Journal, which was published online last night, criticized several previously published InFuse articles for not fully disclosing a large number of InFuse-related serious adverse events. Further, compounding the problem is the fact that ***many of the authors of the prior InFuse studies were also highly paid consultants to Medtronic, thus implying that the conflict of interest played a role.*** Annual sales of InFuse are approximately \$800 million, and we would expect this latest issue to further impact InFuse sales. Each \$100 million of InFuse sales would negatively impact EPS by approximately 3c (or 1%).

* * *

The original trials showed no adverse events or no “unanticipated” adverse events. In contrast, the reanalyzed data showed adverse event rates from 10% to 50% depending on the study and application of InFuse. In addition, the article suggests that the trials may have been designed in such a way as

to introduce bias against the control group and make Infuse results appear more favorable.

112. On June 28, 2011, Medtronic filed its FY11 Form 10-K with the SEC. The Form 10-K was signed by Ishrak and Ellis. The Form 10-K included the same financial results previously reported in the Company's May 24, 2011 press release. The Form 10-K also included a statement about *The Spine Journal* articles, and conceded that the articles would have an impact on future sales:

Looking ahead, we expect our Restorative Therapies Group should be impacted by the following:

* * *

Any effects on our business from discussions in the medical literature, or inquiries from governmental authorities, relating to our INFUSE Bone Graft product. *In June 2011, articles in a medical journal suggested that some physicians' peer-reviewed studies may have underreported complications and adverse events associated with INFUSE.*

113. On these disclosures of June 28, 2011, Medtronic's stock declined \$0.92 per share to close at \$38.09 per share on June 29, 2011, a one-day decline of nearly 3% on volume of 10 million shares.

Independent Analysts' Reviews Disclose More Significant Financial Risks – Stock Price Declines Again

114. On July 5, 2011, Wells Fargo issued a report titled "Spine Journal Article Represents Tip of Iceberg – Downgrading Shares Downgrading to Market Perform." The report indicated that research since the disclosures on June 28, 2011, including surveys of surgeons, indicated the likely impact of the disclosures on the Company's sales and ultimately the stock price:

Summary: We believe the InFuse papers published in The Spine Journal of June 28 will have broader implications for MDT and its spine business than the Street currently expects. . . . We are lowering our valuation range to \$36-37 from \$46-47 which assumes 10x our new CY2012 EPS estimate.

* * *

The Spine Journal Papers Will Result In A Faster And Steeper Decline In InFuse Sales Than We Expected.

We believe The Spine Journal papers will reduce InFuse sales by 30-50% in F2012 because (1) hospitals will push back on InFuse use because of liability concerns; (2) payers are not going to want to pay for InFuse; (3) patients will refuse to be treated with InFuse; and (4) some spine surgeons will feel betrayed because the evidence provided to them was not complete.

* * *

We now estimate that InFuse will ***decline 40%*** in F2012 with a portion of the lost InFuse sales being captured by MDT's demineralized bone matrix (DBM) products (see Figure 3 for our current and prior Biologics estimates).

We Expect The InFuse Issues To Negatively Impact MDT's Spinal Instrumentation Business. . . We believe the instrumentation reps have lost some credibility with surgeons due to The Spine Journal papers. In addition, ***we think spine surgeons will use other bone growth products in their fusion procedures . . . We See About A 25% Chance InFuse Is Pulled From The Market.*** . . . Class Action Lawsuits May Emerge – Uncertainty Over Final Settlement Could Create An Overhang. We expect plaintiff's attorneys to attempt to show that InFuse was used widely because of off label promotion (see DOJ investigation above).

115. Also on July 5, 2011, J.P. Morgan issued a report titled "Medtronic; What the Docs Are Saying on Infuse: Early Feedback Suggests Significant Franchise Risk." The report detailed the doctors' views of the June 28, 2011 *The Spine Journal* reports. J.P. Morgan reported that its surveys indicated the risks to the Company's financial condition:

Medtronic; What the Docs Are Saying on Infuse: Early Feedback Suggests Significant Franchise Risk

Last Tuesday (6/28) *The Spine Journal* released a scathing criticism of Medtronic's Infuse. In an entire issue dedicated to the subject, the editors asserted (1) systematic underreporting of adverse events in the clinical studies supporting Infuse's US approval, (2) faulty trials designs, and (3) widespread financial conflicts of interest among the surgeons who participated in the studies and reported the results. In the wake of these accusations, we surveyed 48 high-volume US spine surgeons to gauge what impact these articles might have on Infuse utilization going forward. ***The results confirm that Medtronic's biologics franchise is at significant risk, with average utilization among our respondents expected to fall by 26% over the next year.***

* * *

Of the 48 surgeons we surveyed, 63% expect to reduce their Infuse usage in the coming year. But that figure jumps to 90% when we sample those surgeons that have actually read the *TSJ* articles; among this group the decline is 54%—double the overall rate.

116. After the July 5, 2011 publication of the securities analyst reports discussing additional financial risks resulting from the June 28, 2011 disclosures, Medtronic's stock price declined further from a close of \$39.12 on July 1, 2011, to \$37.96 on July 5, 2011, on volume of 9.9 million shares traded.

117. On August 3, 2011, Medtronic announced it would publicly release INFUSE data for Yale researchers to conduct a review. Medtronic agreed to pay Yale \$2.5 million to assemble a steering committee, hire two research organizations to review studies of the INFUSE product, and design a database that could be used by outsiders to get access to the information. Harlan Krumholz, Professor of Internal Medicine, Epidemiology, and Public Health at Yale, who was to lead the work, noted: ““It’s a historic agreement and one I hope will set a standard for everyone else in the industry For too long we’ve been in a situation where questions are raised about the safety of a product but companies don’t share the information.””

118. *Bloomberg News* noted that:

While it is a good first step, questions will remain after the analysis is done, [Carragee] said. Infuse is predominantly used in surgeries that haven't been studied by Medtronic, Carragee said. Thus, the two reviews and the database won't provide any clear answers for those patients, he said.

"They simply are not going to have enough data on the main usage of it to give a really precise estimate of how safe or dangerous it is," said Carragee, who is editor in chief of the Spine Journal and led the publication's review of Infuse.

The main problem with the published Infuse trial results is that they didn't include the product's complications, Carragee said. Surgeons didn't know to look for things like cancer and male sterility, he said. That will reduce the number of cases reported to the company and U.S. Food and Drug Administration, and they won't show up in the analysis, he said.

Diminished Accuracy

"The accuracy of that has been severely impacted by 10 years of telling everybody that there are no problems," he said. "I never reported a male sterility event to the company or the FDA because I didn't think it was a complication of the product. It's the same thing for infections or cancer or bladder problems. It was all news to us."

119. On this news, Medtronic's stock declined \$1.47 per share to close at \$32.84 per share on August 4, 2011, a one-day decline of nearly 4% on volume of 11.5 million shares.

POST CLASS PERIOD EVENTS AND ADMISSIONS

120. Following the June 28, 2011 disclosures and Medtronic's announcement on August 3, 2011 that it would release the INFUSE data to Yale, Yale commissioned two separate, independent, systematic reviews of individualized patient data from *all* Medtronic-sponsored clinical studies of INFUSE and AMPLIFY, whether or not that data had been published or submitted to the FDA. Those reviews, conducted by Oregon Health Sciences University ("OHSU") and University of York ("York"), sought to answer the question:

compared with iliac crest bone grafting, does rhBMP-2 safely improve outcomes of spinal fusion surgery? The answer: a resounding ***no***.

121. The results of the reviews appeared in the June 2013 issue of *Annals of Internal Medicine*, and confirmed the assertions made in *The Spine Journal* two years earlier. As noted in the editorial accompanying the reviews:

[A]fter systematic evaluation and synthesis of all available evidence, both systematic reviews published here independently conclude that ***rhBMP-2, compared with iliac crest bone grafting, does not improve pain or function and increases adverse events, possibly including cancer.***

122. The York review found that rhBMP-2 patients ***had more adverse events than ICBG patients***, including pain, difficulty swallowing, infection, and retrograde ejaculation, among many others. Further, while there was evidence of “small improvements” in fusion success and a non-significant reduction in pain level at 6 months postoperatively with rhBMP-2, these nominal improvements “c[a]me at the expense of more frequent pain in the immediate postoperative period and, possibly, an increased number of cancer cases.”

123. The OHSU review reached the same conclusions, stating pointedly that “[i]n spinal fusion, rhBMP-2 has ***no proven clinical advantage*** over bone graft and may be associated with important harms, making it difficult to identify clear indications for rhBMP-2.” Even more striking was OHSU’s pronouncement that “[e]arlier disclosure of all relevant data would have better informed clinicians and the public than the initial published trial reports did.” Noting that they had “unusual access” to Medtronic’s data and protocols, the reviewers suggested that Medtronic and its paid consultants had published “***an incomplete and sometimes misleading evidence base***” in favor of INFUSE.

124. On June 17, 2013, *The Spine Journal* published an article reacting to the Yale University Open Data Project Report published on the same day. That report confirmed the findings in the June 28, 2011 *The Spine Journal* and Carragee offered these final comments:

Response to Long-Awaited YODA Report on Controversial Spinal Fusion Product

The YODA (Yale University Open Data Access Project) report published today in the Annals of Internal Medicine is the latest and saddest shock to Medtronic's biologics product, human recombinant bone morphogenetic protein-2 (InFuse and other formulations). YODA's two independent groups found that "*rhBMP-2 provided little or no benefit compared to bone graft and may be associated with more harms, possibly including cancer...*" But what is even more troubling, the groups found that the Medtronic-associated authors "*misrepresented*" efficacy and underreported complications "*for both on-label and off-label indications*" and "*selected analyses and results that favored rhBMP-2 over ICBG*." The YODA groups confirm the findings of *The Spine Journal*'s editorial review of 2011.

* * *

Years following FDA approval, Dr. Boden reported unparalleled product safety, "the only known risk [of on-label use] involves development of transient increases in antibodies." Even more emphatically, the author of many industry-sponsored publications, Dr. Burkus reported that "[n]o adverse events have been linked to the use of rhBMP-2." Regarding the same early work by Burkus and Zdeblick the YODA group finds: "*Early journal publications misrepresented the effectiveness and harms through selective reporting, duplicate publication and underreporting*."

* * *

In some instances, it seems investigators with strong financial ties helped design a trial, and then acted as surgeons who monitored their own complications. To complete the circuit the same surgeon/investigator would co-author the paper and then submit the manuscript for review to...well...*himself* as chief or section editor of the journal. In some cases the editor in chief of the journal approving his own paper was also the developer and the royalty holder on products being investigated. It would be hard to envision a situation more likely to produce, as the YODA group found, "*journal publications select[ing] analyses and results that favored rhBMP-2 over ICBG*."

* * *

It is ultimately disappointing that after 15 years of largely self-congratulatory research, we have only indirectly discovered BMP-2's many potential complications. At present these "concerns" regarding higher rates of cancer, sterility, wound problems and nerve injury remain poorly described. ***The suggested reason for this gap in our understanding, if true, is simply appalling: these complications were systematically "misrepresented," "underreported," or just "missing" from the first decade of publications.***

(Emphasis added and in original).

The United States Senate Committee on Finance Issues a Report Corroborating Disclosures Made by the June 28, 2011 Edition of *The Spine Journal* and Confirming Allegations Herein

125. In October 2012, the U.S. Senate Committee on Finance issued a staff report on Medtronic's influence on INFUSE clinical studies. The Senate Report, issued after the Committee spent more than a year reviewing documents and e-mails produced by Medtronic, made the following findings:

- Medtronic was heavily involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure industry role contributions be fully disclosed.
- Medtronic paid a total of approximately \$210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other miscellaneous arrangements.
- An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events possibly associated with INFUSE in a 2005 *Journal of Bone & Joint Surgery* article.
- Medtronic officials inserted language into studies that promoted INFUSE as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique.
- Documents indicate that Medtronic prepared Dr. Hal Mathew's remarks to the FDA advisory panel meeting prior to INFUSE being approved. At the time,

Dr. Mathews was a private physician but was hired as a vice president at Medtronic in 2007.

- Medtronic documents show the Company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying INFUSE in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

Ex. C at 2.

126. First, with respect to the non-disclosure of adverse events, the Senate Report provided the following example of its findings with respect to INFUSE:

On June 16, 2004, Dr. Julie Bearcroft, Director of Technology Management in Medtronic's Biologics Marketing Department, wrote an e-mail to other Medtronic employees, commenting on a draft of the study, "I have made some significant changes to this document (some at the request of Dr. Burkus) both in format and content." In this e-mail, she asked: "How much information should we provide relative to adverse events? . . . You will see my [note] in the attached document but I don't think significant detail this section is warranted." The referenced note in the draft article on stated: "I don't believe we want to report in the same manner as we do in IDE studies. I personally think it is appropriate to simply report the adverse events were equivalent in the two groups without the detail."

Id. at 9.

127. Certain of the Senate Report findings also confirmed that, with respect to the adverse events known to the Company, Medtronic employees specifically crafted the content and the reporting format of the adverse events with the specific intent to conceal or at least obscure the true adverse events' rate of incidence associated with INFUSE:

According to an internal e-mail, the adverse events were observed in the trial and formatted in a detailed table. But following the advice of Bearcroft, this table of adverse events was not included in the published paper.

On July 3, 2004, after Medtronic edited the paper, Dr. Burkus sent a draft to his co-authors writing that "this manuscript documents the superiority in clinical and radiographic outcomes with the use of rhBMP2 in a study population of only 133 patients."

According to the Carragee et al. *Spine Journal* article published in 2011, the 2005 *JBJS* article “reported no complications, such as end-plate fracture, collapse, and implant migration associated with rhBMP–2 despite the clear radiographic findings in at least the one presented case.” The e-mail exchange indicates that, in addition to Medtronic ***editing the manuscript without attribution, the company was recommending that the article omit a complete accounting of adverse event data, including serious adverse event data that were already considered a documented concern by FDA in similar application.***

These types of adverse events were disclosed in Table V of a 2009 follow-up article concerning the original IDE study. Studies published in 2007 revealed that InFuse is associated with “a clinically important early inflammatory and osteoclastic effect of the rhBMP–2 in soft tissue and bone, respectively.” In other words, Medtronic recommended against including information in the study that was ultimately revealed to have an association between In-Fuse and weakening that could lead to collapse of the bone and implant and required that patients undergo additional surgery.

... The adverse events observed in the allograft trial were observed and formatted in a table, but following the advice of Bearcroft, the table was not included in the published paper.

Id. at 9-10.

128. The Senate Report also discussed an example of its findings wherein Medtronic attempted to downplay side effects of using rhBMP-2 and to attribute side effects such as retrograde ejaculation to a surgical technique as opposed to INFUSE, knowing that incidence of retrograde ejaculation had a 10.3% rate in the investigational group compared to a 1.5% rate for the control group:

In his 2011 *Spine Journal* article, Dr. Carragee reported that “multiple independent studies have found that the rate of [retrograde ejaculation (a condition that causes sterility)] in ALIF with rhBMP–2 is approximately 5% to 7% and possibly two to four times higher than the rate observed without rhBMP–2.” However, the physician authors who reported the clinical results of a major Medtronic-sponsored study in the *Journal of Spinal Disorders and Techniques* attributed the adverse event to the surgical technique used without comparing the investigational study group receiving InFuse to the control group. Dr. Carragee told the *New York Times* that the omission is significant

because “[i]t is important that men who are considering having children have the opportunity to weigh the risks of the various available procedures.”

A February 2001 PowerPoint presentation indicates that Dr. Zdeblick was aware that retrograde ejaculation rates were higher in both investigational groups than the control group. In a PowerPoint presentation to study investigators in February 2001, Dr. Zdeblick reported a 10.3% rate of retrograde ejaculation using the laparoscopic technique, a 6.3% for patients who underwent an “open” technique, and a 1.5% rate for the control group. The 10.3% rate was noted in the presentation to be “[s]tatiscally different from [the] control [group].

Id. at 14-15.

129. Finally, the Senate Report describes at least one instance in which the Company and its executives wrote responses to peer reviews as opposed to the author drafting responses to peer reviews:

Medtronic Wrote Author Responses to Peer-Review

E-mail exchanges between Dr. Burkus and Medtronic employee regarding a study of InFuse utilizing the posterior lumbar interbody fusion (PLIF) technique and published in *The Spine Journal* in 2004 demonstrates that *Medtronic employees not only edited the draft manuscript to include comments supportive of InFuse, they also covertly participated in the peer-review process by drafting responses to peer-reviewers on behalf of the physician authors named on the paper.*

* * *

In a January 10, 2003, e-mail to Dr. Burkus, Rick Treharne wrote, “In looking over the data, I was impressed with how well the BMP patients actually did. So much so that I added a few paragraphs at the end that you may not agree with.” In the draft article, Treharne wrote: “In conclusion, this detailed, *independent review of the results*, which represent the first use of osteoinductive proteins in a PLIF procedure, are encouraging. These findings along with other studies for other indications imply that future larger PLIF studies with BMP-2 are needed. In future studies using modified surgical techniques, such as using more recessed cages to allow for extra posterior bone formation, adding steps to minimize bleeding, and/or adding secondary instrumentation may be beneficial. Further, *possibly modifying patient selection, such as entering patients with less vertebral slip, may also help*

minimize confounding variables. All of these changes may produce even better, more convincing evidence that INFUSE Bone Graft can also be used as substitute for autograft in PLIF procedures.”

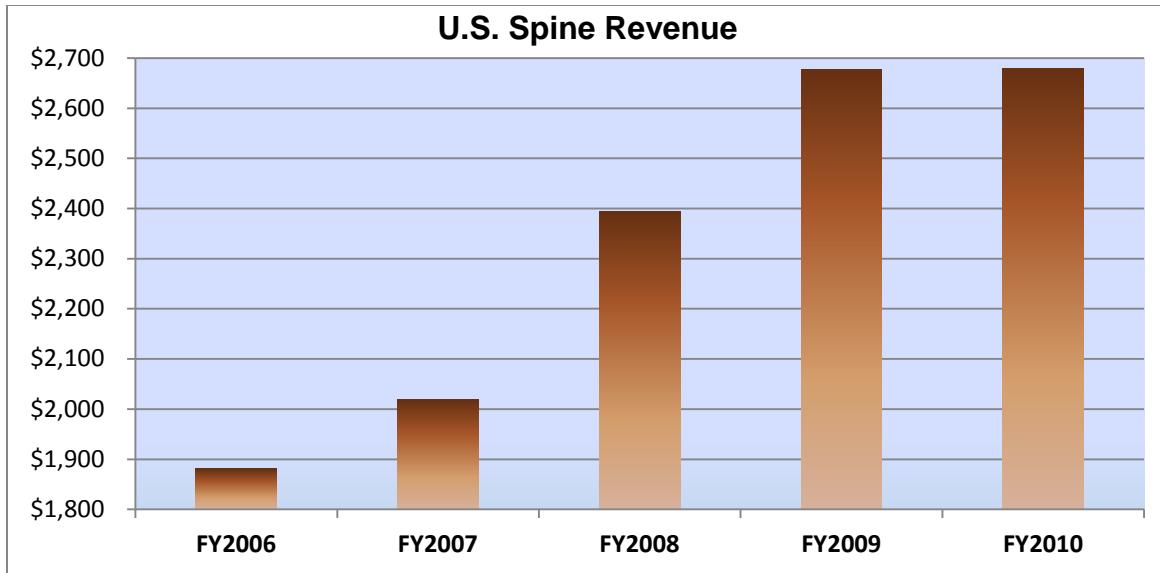
On February 1, 2003, Dr. Burkus e-mailed another draft of the BMP manuscript to Medtronic officials asking for “final comments.” On March 7, 2003, Julie Bearcroft e-mailed Dr. Burkus an updated version of this manuscript with her proposed changes to the draft.

After submission of the initial draft of this study to *The Spine Journal*, physicians who peer-reviewed the article were critical of its presentation of the study results. One reviewer wrote: “Unless the authors can discuss the results of this study in an unbiased manner, which they have been unable to do in its present form, this data should not be published.” Another reviewer wrote: “The manuscript is full of biased statements that are a reflection of the data evaluators—the company that markets the product.” That reviewer recommended a discussion of potential bias in the text of the paper writing, “As it stands it is an advertisement for a specific product without significant scientific merit.”

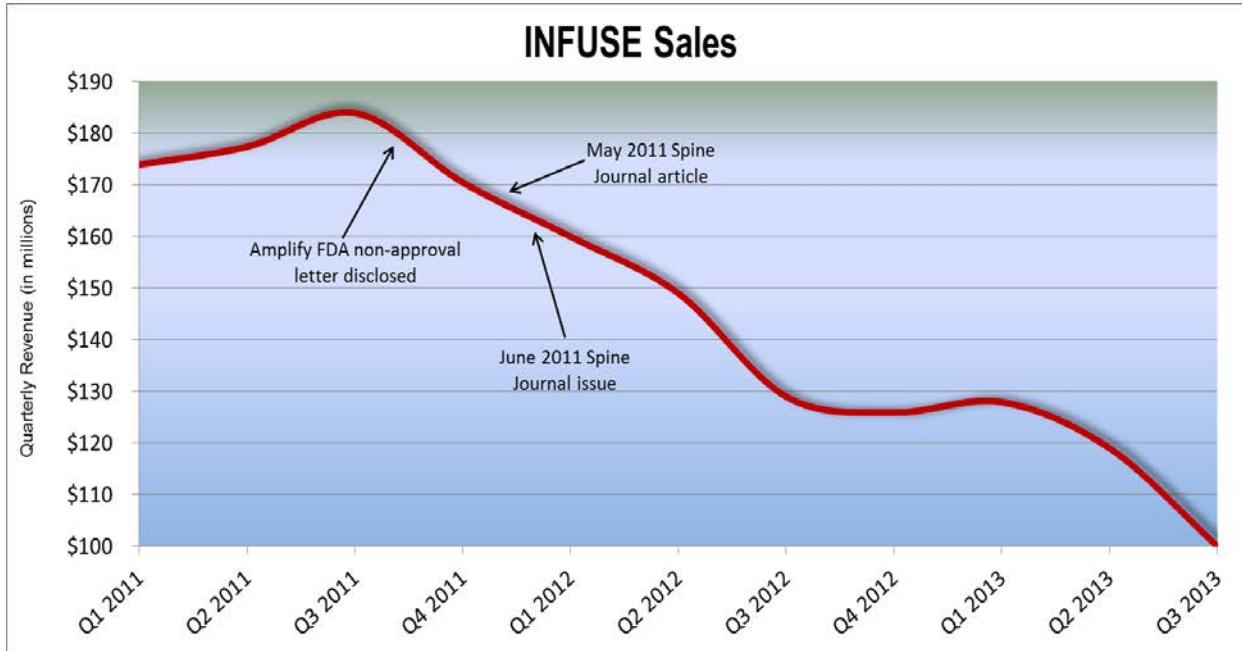
Id. at 15-16.

MEDTRONIC’S CLASS PERIOD FINANCIAL STATEMENTS VIOLATED SEC DISCLOSURE RULES

130. Prior to and during the Class Period, Medtronic reported several years of sequential revenue growth in its U.S. Spine segment. During this time frame, defendants frequently emphasized the Spine segment as an important revenue growth driver for the Company as a whole:



131. Throughout the Class Period, defendants knew that when the truth about INFUSE emerged, the Company would suffer material declines in sales. Indeed, as the news about Medtronic's deceptive marketing practices and the INFUSE safety risks were revealed, the Company's sales of INFUSE plummeted. As shown in the chart below, INFUSE sales have declined significantly since 3Q11:



132. Defendants violated SEC disclosure rules, notably Regulation S-K Item 303(a)(3)(ii), in the Management's Discussion and Analysis ("MD&A") section of the Company's Class-Period financial statements by presenting a positive trend of increasing Spine segment and INFUSE (Biologics) revenue without any further disclosure that the reported results were in no way indicative of future results.

133. Regulation S-K Item 303(a)(3)(ii) requires companies to:

Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.

* * *

The discussion and analysis shall *focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results . . .*

134. The SEC has stated that "[d]isclosure is mandatory where there is a known trend or uncertainty that is *reasonably likely* to have a material effect on the registrant's financial condition or results of operations."⁹ Other SEC interpretations and guidance have clarified the SEC's position. For example:

- "One of the principal objectives of MD&A is to provide information about the quality and potential variability of a company's earnings and cash flow, so that readers can *ascertain the likelihood that past performance is indicative of future performance*. Ascertaining this indicative value depends to a significant degree on the quality of disclosure about the facts and

⁹ Securities Act Release No. 6835 (May 18, 1989), Management's Discussion and Analysis of Financial Condition and Results of Operations.

circumstances surrounding known material trends and uncertainties in MD&A.”¹⁰

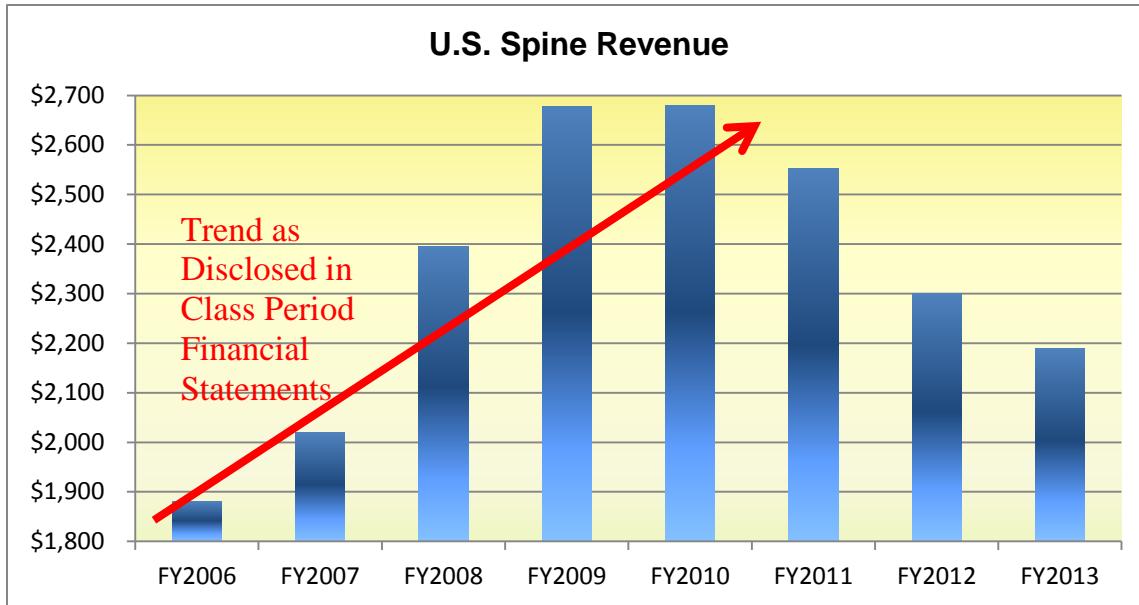
- “The MD&A requirements are intended to provide in one section of a filing, material historical and prospective textual disclosure enabling investors and other users to assess the financial condition and results of operations of the registrant, *with particular emphasis on the registrant’s prospects for the future.*”¹¹

135. Defendants knew or acted with deliberate recklessness of the fact that revealing the truth about INFUSE would have a “*material...unfavorable impact on...revenues*” going forward. Defendants knew that the imminent decline in INFUSE’s market share was certain to “cause reported financial information” contained in the Company’s Class-Period financial statements (*i.e.*, the trend shown in the chart below) to “not be . . . indicative of future operating results.”¹²

¹⁰ Securities Act Release Nos. 33-8350 & 34-48960 (Dec. 29, 2003), Commission Guidance Regarding Management’s Discussion and Analysis of Financial Condition and Results of Operations.

¹¹ Securities Act Release No. 6835, *supra*.

¹² Defendants admitted that as of June 2011, before *The Spine Journal* issue was published, they were already anticipating INFUSE sales to decline. On the June 9, 2011 Goldman Sachs Global Healthcare Conference call: “[T]he reality is our assumptions are that INFUSE would be slightly down and be under some pressure here over this next year. That’s baked into our guidance at this point in time, that you will continue to see INFUSE being slightly down as we go forward.”



LOSS CAUSATION/ECONOMIC LOSS

136. Plaintiffs incorporate by reference the allegations in ¶¶69-119 set forth above.

137. Prior to and during the Class Period, defendants engaged in a scheme to defraud and issued material, false and misleading statements concerning the Company's true financial condition. Specifically, as alleged herein, the Company knowingly misrepresented and intentionally concealed the known safety risks associated with its top-selling spinal surgery treatment INFUSE. As part of the scheme, which continued during the Class Period, defendants: (i) caused materially false and misleading statements concerning the safety and efficacy of INFUSE to be published in the medical journals, while failing to disclose known adverse side effects; (ii) paid millions to physician consultants and authors of the publications that were not fully disclosed; and (iii) drafted and/or heavily edited research articles to exclude significant adverse side effects of INFUSE.

138. The conduct alleged herein and the materially false and misleading statements made during the Class Period caused Medtronic's common stock to trade at inflated prices as

high as \$43.20 per share during the Class Period – and operated as a fraud or deceit on investors in the Company’s common stock.

139. Later, when the relevant truth was disclosed regarding defendants’ conduct, including FDA rejection of INFUSE-related product AMPLIFY, the true safety risks associated with INFUSE and the significant financial ties between the Company and the physician authors who published the early articles (which failed to mention any of the adverse side effects and events caused by INFUSE), Medtronic’s stock price suffered significant declines, as the artificial inflation came out of the stock price.

140. For example, on March 9, 2011, the Company filed a Form 10-Q which disclosed that the FDA had rejected its new INFUSE-related treatment AMPLIFY, and that the rejection had occurred in the third quarter of Medtronic’s fiscal 2011, well before the February 22, 2011 investor conference call during which defendants were asked about the status and potential delay of approval of AMPLIFY and defendants failed to disclose the fact the Company had already been rejected. While some analysts had built in the possibility of rejection in their models, some investors hoped it would be approved. This disclosure was a substantial cause of the Company’s stock price decline from \$39.80 on March 9, 2011 to a close of \$38.63 on March 10, 2011.

141. On May 25, 2011, *The Spine Journal* published a clinical study titled “Retrograde Ejaculation After Anterior Lumbar Interbody Fusion Using rhBMP-2: A Cohort Controlled Study” which disclosed a significant link between INFUSE and the development of retrograde ejaculation. ¶¶89-90; Ex. G. *The Spine Journal*’s findings were quickly reported by *Bloomberg* and *The New York Times*. ¶¶91-92. These disclosures were a

substantial cause of the Company's stock price decline from a close of \$40.88 on May 24, 2011, to a close of \$40.23 on May 25, 2011. Notwithstanding this disclosure, the Company and Zdeblick issued additional material knowingly false and misleading statements, falsely denying that the early clinical studies relating to INFUSE had shown any statistically significant or statistically different risk of retrograde ejaculation, and that retrospective analyses such as the one reported in *The Spine Journal* were "notorious for being misleading." ¶¶93, 96, 97. Nevertheless, securities analysts noted that the new information and "greater awareness of the association of retrograde ejaculation with INFUSE could significantly reduce INFUSE sales." ¶94. As a result of defendants' continued denials, the stock continued to trade at artificially inflated prices.

142. On June 28, 2011, *The Spine Journal* published an entire issue devoted to the results of new studies of INFUSE, including the apparent statistical significance of an even broader array of adverse effects associated with the use of INFUSE. ¶¶103-108. The June 28, 2011 *Spine Journal* also highlighted financial conflicts of interest by researchers who had performed early studies and drafted the peer reviewed early medical journal articles on INFUSE. ¶¶103-106. The June 28, 2011 *The Spine Journal* also emphatically and scientifically indicated that the research and clinical studies supporting the safety and efficacy of INFUSE appeared to be biased in favor of INFUSE. ¶104. Securities analysts commenting on this news noted that *The Spine Journal's* articles "represent[ed] an unprecedented attack on the quality of the research used to support Infuse's approval." See ¶¶110, 111. These disclosures were a substantial cause of the Company's stock price decline

of \$0.92 per share to close at \$38.09 per share on June 29, 2011, a one-day decline of nearly 3%. ¶¶33, 113.

143. On July 5, 2011, several securities analysts issued reports containing new information concerning the financial and economic impact *The Spine Journal*'s June 28, 2011 disclosures. ¶¶114-115. For instance, Wells Fargo downgraded Medtronic stock, stating that *The Spine Journal*'s reports would "reduce InFuse sales by 30%-50% in [FY12]." ¶114. J.P. Morgan issued a report which included a new survey of 48 high-volume U.S. spine surgeons to "gauge what impact these articles might have on InFuse utilization going forward" and reported that **90%** of surgeons who read *The Spine Journal* articles planned to reduce utilization of INFUSE by 54%. ¶115. These reports and disclosures were a substantial cause of the Company's stock decline from a close of \$39.12 on July 1, 2011, to \$37.96 on July 5, 2011. ¶116.

144. On August 3, 2011, Medtronic entered into an unprecedented agreement with Yale University to pay Yale \$2.5 million to review data from all INFUSE and AMPLIFY clinical studies and to design a database that could be used by outsiders to get access to the information. ¶117. This agreement was a tacit acknowledgement that the Company's trust in the integrity of its clinical research regarding INFUSE had been credibly damaged. This news caused Medtronic's stock price to decline \$1.47 per share to close at \$32.84 per share on August 4, 2011, a one-day decline of nearly 4%.

145. Like other members of the Class of purchasers of Medtronic common stock who purchased at artificially inflated prices during the Class Period, plaintiffs suffered an economic loss, *i.e.*, damages, when Medtronic's stock price declined following the

disclosures on March 9, 2011, May 25, 2011, June 28, 2011, July 5, 2011 and August 3, 2011 regarding defendants' scheme to conceal Medtronic's true financial condition and material adverse facts about INFUSE and AMPLIFY.

NO SAFE HARBOR

146. Medtronic's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

147. Defendants are also liable for any false or misleading FLS pleaded because, at the time each an FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Medtronic who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

148. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;

- (c) The Company's stock traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and
- (e) Plaintiffs and other members of the Class purchased Medtronic common stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

149. At all relevant times, the market for Medtronic common stock was efficient for the following reasons, among others:

- (a) As a regulated issuer, Medtronic filed periodic public reports with the SEC; and
- (b) Medtronic regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major newswire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

CLASS ACTION ALLEGATIONS

150. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Medtronic common stock during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which defendants have or had a controlling interest.

151. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Medtronic has over 1 billion shares of stock outstanding, owned by hundreds if not thousands of persons.

152. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) whether defendants violated the 1934 Act;
- (b) whether defendants engaged in a fraudulent scheme;
- (c) whether defendants omitted and/or misrepresented material facts;
- (d) whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (e) whether defendants knew or recklessly disregarded that their statements were materially false and misleading;
- (f) whether reliance may be presumed pursuant to the fraud-on-the-market doctrine or presumption;
- (g) whether the price of Medtronic common stock was artificially inflated; and
- (h) the extent of damage sustained by Class members and the appropriate measure of damages.

153. Plaintiffs' claims are typical of those of the Class because plaintiffs and the Class sustained damages from defendants' wrongful conduct.

154. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiffs have no interests which conflict with those of the Class.

155. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this case as a class action.

156. Plaintiffs make the allegations herein based upon the investigation of plaintiffs' counsel, which included a review of regulatory filings made by Medtronic with the SEC, as well as other regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

COUNT I
(False and Misleading Statements)

**Violation of Section 10(b) of the Exchange Act
and Rule 10b-5(b) Promulgated Thereunder
Against Medtronic, Hawkins, Ellis, Kuntz and Zdeblick**

157. Plaintiffs incorporate by reference and reallege each and every allegation contained above as if fully set forth herein.

158. During the Class Period, defendants made false and misleading statements of material fact, and omitted material facts necessary to make the statements about Medtronic's operations and prospects, in light of the circumstances under which they were made, not misleading, specifically, the statements referenced at ¶¶70-73, 78, 85, 96-97.

159. In addition to the duties of full disclosure imposed on defendants as a result of their affirmative statements and reports, or participation in the making of their affirmative statements and reports to the investing public, defendants had a duty to promptly disseminate truthful information that would be material to investors, in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulations, including truthful, complete and accurate information with respect to the Company's operations and financial condition so that the Company's share price would be based on truthful, complete and accurate information.

160. The allegations above establish a strong inference that defendants acted with scienter throughout the Class Period, as they had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis. By concealing these material facts from investors, Medtronic maintained its artificially inflated share price throughout the Class Period.

161. By virtue of the foregoing, defendants have violated §10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

COUNT II
(Scheme Liability)

**Violation of Section 10(b) of the Exchange Act
and Rule 10b-5(a) and (c) Promulgated Thereunder
Against All Defendants**

162. Plaintiffs incorporate by reference and reallege each and every allegation contained above as if fully set forth herein.

163. As early as 2001 and continuing through the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, did: (i) deceive the investing public, including plaintiffs and other members of the Class, as alleged herein; (ii) enable Medtronic to artificially inflate the price of Medtronic's common stock; and (iii) cause plaintiffs and other members of the Class to purchase Medtronic's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants took the following actions:

- (a) drafted, edited and shaped the content of medical journals purporting to convey clinical evidence in support of INFUSE's safety and benefits;
- (b) concealed, or caused others to conceal, significant adverse side effects associated with the use of INFUSE for both approved and unapproved indications;
- (c) overstated, or caused others to overstate, the disadvantages of alternative bone-graft procedures in order to create the false impression of INFUSE's superiority over those procedures;
- (d) paid physicians, consultants and other agents, whose expertise and experience would influence the medical community to induce their complicity in concealing

adverse events and side effects associated with the use of INFUSE and overstating the disadvantages of alternative bone graft procedures; and

(e) issued false and misleading statements as alleged in ¶¶70-73, 78, 85, 93, 96-97 in furtherance of the scheme.

164. Each and every defendant is sued as a primary participant in the wrongful and illegal conduct charged herein.

165. The scheme and course of conduct alleged herein was intended to, and did, drive sales of INFUSE and with it, Medtronic's profits and share price.

**COUNT III
(Control Persons)**

**For Violation of Section 20(a) of the 1934 Act
Against Medtronic and the Individual Defendants**

166. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

167. Each of the Individual Defendants acted as a control person of the Company within the meaning of §20(a) of the Exchange Act (15 U.S.C. §78t(a)), as alleged herein. By virtue of their stock ownership, high-level positions, and participation in and/or awareness of the Company's operations, finances and research, each individual defendant had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiffs contend are false and misleading. Each Individual Defendant was provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be misleading prior to and/or shortly

after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

168. Each Individual Defendant had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control Medtronic's public statements and participation in the alleged fraudulent scheme as alleged herein, and exercised the same. Further, each of the Individual Defendants had unlimited access to data, reports and results generated from clinical trials of INFUSE and AMPLIFY. Defendants Hawkins, Ellis, Kuntz, Bearcroft, Treharne and Yahiro had the power and ability to control (and did influence and control, directly or indirectly) the actions of Medtronic and its employees, including their participation in the alleged fraudulent scheme and directing the content of Medtronic's financial statements, releases and conference call statements.

169. Medtronic controlled the Individual Defendants and all of Medtronic's employees and directors.

170. By reason of such wrongful conduct, Medtronic and the Individual Defendants are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs pray for relief and judgment as follows:

- A. Determining that this action is a proper class action and certifying plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and plaintiffs' counsel as Lead Counsel;
- B. Awarding plaintiffs and the members of the Class damages, including interest;
- C. Awarding plaintiffs' reasonable costs and attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury.

DATED: November 4, 2013

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